Comparison of McGrath Mac laryngoscope and Macintosh laryngoscope video for intubation in the ICU.

McGrath Mac laryngoscope versus Macintosh laryngoscope video for orotracheal intubation in critical care unit.

Study code: MACMAN

VERSION No. 6.0 on June 25, 2015

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<table>
<thead>
<tr>
<th>INSTITUTION RESPONSIBLE FOR THE RESEARCH:</th>
<th>CHD Vendée</th>
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<tr>
<td><strong>CLINICAL TRIAL PROTOCOL</strong></td>
<td>MACMAN</td>
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<tr>
<td><strong>TEST CODE</strong></td>
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<tr>
<td><strong>STRATEGY</strong></td>
<td>Performing tracheal intubation in the ICU using one of the two following devices at random: Video laryngoscope or Macintosh laryngoscope. 2014-A00674-43</td>
</tr>
<tr>
<td>Registration No.</td>
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<tr>
<td><strong>FULL TITLE</strong></td>
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<tr>
<td><strong>CLINICAL PHASE</strong></td>
<td>N/A</td>
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<tr>
<td><strong>INDICATION(S) (TARGET)</strong></td>
<td>Emergency intubation in the ICU.</td>
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<tr>
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</tr>
<tr>
<td><strong>PROTOCOL VERSION No.</strong></td>
<td>6.0</td>
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<td><strong>DATE OF PROTOCOL</strong></td>
<td>06/25/2015</td>
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<tr>
<td><strong>CPP (IRB - Institutional Review Board)</strong></td>
<td>Approved By the Institutional Review Board West II in Angers</td>
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<tr>
<td><strong>ANSM (French National Agency for Medicines and Health Products Safety)</strong></td>
<td>N/A</td>
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List of abbreviations

BAVU: Auto-inflating balloon with one-way valve
CPP: IRB (Institutional Review Board)
CRF: Functional residual capacity
DTM: Distance thyroid-chin
FiO2: Fraction of inspired oxygen
FeO2: Fraction of expired oxygen
IDS: Intubation difficulty scale
IGS II: Simplified severity index 2
IOT: Orotracheal intubation
ISR: Rapid sequence induction
IVD: Direct intravenous injection
LM: Direct macintosh laryngoscopy
OB: Mouth opening
PAD: Diastolic blood pressure
PEEP: Positive end-expiratory pressure
PetCO2: End-expiratory fraction of expired carbon dioxide
P plat: Plateau pressure
SFAR: French Society of Anesthesia and Intensive Care
SRLF: French Society of Intensive Care
VL: Laryngoscope video
VNI: Non-invasive ventilation
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SIGNATURE OF INVESTIGATOR

I have read all the pages of the clinical trial protocol for which CHD Vendée is the responsible institution. I confirm that it contains all the information needed to conduct the test. I pledge to conduct the trial in compliance with the protocol and the terms and conditions set therein. I am committed to performing the test in accordance with:

- the principles of the "Helsinki Declaration,"
- the rules and recommendations of Good Clinical Practice on an international level (ICH-E6) and in France (rules of good clinical practice for biomedical research involving products for human use - Decision of 24 November 2006)
- national laws and regulations relating to clinical trials,
- compliance with EU Clinical Testing Directive, a copy of which has been provided to me by the institution responsible for the research.

I also agree that the investigators and other qualified members of my team have access to copies of this protocol and documents relating to the conduct of the trial, allowing them to work in compliance with the provisions contained in those documents.

NAME:  
Signature:  
Date:

SIGNATURE OF THE INSTITUTION RESPONSIBLE FOR THE RESEARCH

Institution responsible for the research: CHD Vendée

NAME:__________________________

Signature:...............................................

Date:__________________________
### SUMMARY

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**PROTOCOL VERSION** 6 of 06/25/2015

**JUSTIFICATION/CONTEXT**
Orotracheal intubation is a common procedure performed in the operating room. In this context, it has low morbidity and mortality of almost zero. The prevention algorithms for these complications are codified and are subject to the recommendations of scientific societies (SFAR, SRLF, SFMU). In more than a quarter of resuscitation cases, non-optimal intubation conditions are responsible for an increased incidence of difficult intubation and occasionally severe complications. Certain factors can prevent the occurrence of these complications: systematic vascular filling, use of vasoactive amine, use of VNI for pre-oxygenation and the use of an algorithm in case of difficult orotracheal intubation or mask ventilation. Nevertheless, these precautions do not guarantee the success of the procedure itself, but prevent the side effects associated with the required anesthetics. The recent market introduction of video laryngoscopes (VL), which allow for intubation via video controlled laryngoscopy, represents a possible solution. Indeed, the VL would increase the safety of the procedure due to improved glottal vision and the assistance of a second operator. All of these arguments allow us to hypothesize that the video laryngoscope would increase the proportion of successful orotracheal intubations on the first laryngoscopy attempt when compared with a Macintosh laryngoscope.

**PRIMARY OBJECTIVE**
Demonstrate an increase in the proportion of successful orotracheal intubations for the first laryngoscopy with the video laryngoscope in patients requiring orotracheal intubation and resuscitation with less than 3 criteria for difficult intubation.

**SECONDARY OBJECTIVES**
- Proportion of successful orotracheal intubations for all laryngoscopies
- Length of the procedure before successful orotracheal intubation
- Glottal visibility as defined by the Cormack and Lehane score and the POGO score
- Proportion of difficult intubations (defined by 2 failed laryngoscopies or a duration of more than 10 minutes)
- Use of alternative intubation techniques
- Occurrence of severe complications (desaturation, hypotension, occurrence of vomiting, cardiac arrest, tooth breakage, esophageal intubation)
- Difference in morbidity
- Mortality upon leaving the ICU
- Mortality at Day 28

**PRIMARY EVALUATION CRITERIA**
Proportion of successful orotracheal intubations in the first laryngoscopy performed with the video laryngoscope/Proportion of successful orotracheal intubations in the first laryngoscopy performed with a classic Macintosh laryngoscope.

**SECONDARY CRITERIA:**
- Proportion of successful orotracheal intubations for all laryngoscopies
- Length of the procedure before successful orotracheal intubation
- Comparison of the Cormack score for glottal visibility
- Comparison of the POGO score for glottal visibility
- Proportion of difficult intubations
- Comparing the use of alternative intubation techniques in 2 groups:
  - Use of a long angulated stylet
- Use of a supra-glottal device (Fast-trach®)
- Use of a video laryngoscope (Airtraq® or Glydescope®) validated with the difficult intubation algorithm and/or using a fiberscope.
- Use of a trans-tracheal oxygenation device
- Comparison of the frequency of occurrence of adverse events:
  - Tooth breakage
  - Aspiration of gastric contents
  - Proportion of esophageal intubations
  - Desaturation <90%
  - Hypotension defined as PAS<90mmHg
  - Cardiac arrest
- Comparison of morbidity between the 2 groups:
  - duration of artificial ventilation
  - duration of ICU stay
  - duration of hospital stay
- Mortality upon leaving the ICU
- Mortality at Day 28

### METHODOLOGY/OUTLINE OF THE STUDY
Randomized, multi-centric superiority study conducted openly.

### SUBJECT INCLUSION CRITERIA
- Patient in intensive care requiring mechanical ventilation using an intubation tube.

### CRITERIA FOR NON-INCLUSION OF SUBJECTS
- Counter-indication for orotracheal intubation (including unstable cervical spinal injuries)
- No delay allowing for the inclusion and randomization of the patient (including a heart attack)
- Minor (<18 years)
- Woman that is pregnant, parturient or nursing
- Hospital patient without consent and/or deprived of liberty by the justice system
- Patient under guardianship
- No Social Security
- Refusal of the responsible party or patient
- Patient participation in a research protocol whose primary criteria is based on the intubation procedure

### STRATEGIES/PROCEDURES
The strategy focuses on the use of McGrath Mac video laryngoscope for the realization of orotracheal intubation, which seems beneficial in terms of direct and indirect glottal visibility for tracheal intubation in an emergency situation.

### NUMBER OF PATIENTS
Taking into account that the proportion of patients successfully intubated during the first ICU laryngoscopy will be 65% in the Macintosh group (De Jonghe Intensive Care Medicine 2013; Wang Preshopital Emergency Care 2005), and assuming that the use of the McGrath Mac laryngoscope will achieve a success rate of 80%, and setting an alpha risk of 5% and a beta risk of 10%, it is expected to include 185 patients per group and 370 patients in total.

### INTERMEDIATE MONITORING AND ANALYSIS COMMITTEE
No independent oversight committee nor planned intermediate analysis.

### DURATION OF RESEARCH
Duration of inclusions: 12 months
Duration of statistical analysis: 3 months
Duration of report drafting: 3 months
Duration of research: 2 months
<table>
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<tr>
<th>EXPECTED RESULTS</th>
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<tr>
<td>If the main hypothesis is confirmed, orotracheal intubation through the McGrath Mac video laryngoscope will become a reference technique in urgent care, leading to a reduction in the failure rate for the 1st laryngoscopy and a decrease in the proportion of difficult intubations. It will be associated with improved safety for patients by avoiding a lengthy procedure and the potential occurrence of serious complications (deep hypoxemia episodes, cardiac arrest). This device could also be used in centers or services where intubation in an emergency (ambulance, emergency services) is a common technical act that presents significant morbidity to the patients concerned.</td>
</tr>
</tbody>
</table>
I. General information

A. Title

MACMAN Study,
Comparison of McGrath Mac video laryngoscope and Macintosh laryngoscope for intubation in the ICU.
McGrath Mac video laryngoscope versus Macintosh laryngoscope for orotracheal intubation in critical care unit.

B. Coordination and monitoring of the study

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II. Rationale and general description of research

A. Result summary of non-clinical and clinical trials available and relevant in light of the concerned biomedical research

Intubation involves inserting a prosthesis into the trachea in order to connect a mechanical ventilation device (respirator) to a patient in need, because the patient’s own lungs no longer function or because the patient is in a coma.

In the ICU, this involves an urgent procedure performed on a patient suffering from organ failure. This organ failure (hemodynamic, respiratory or neurological) is associated with a functional pulmonary reserve in reduced oxygen of a multifactorial origin (decreased functional residual capacity, increased oxygen consumption and decreased oxygen delivery and tissue extraction capacity in case of shock and/or sepsis). In addition, patient positioning during the procedure (raised head, cervical spine mobility, ...) is more difficult than in the operating room and can lead to a misalignment of the oro-pharyngolaryngeal axis during the laryngoscopy.

The failure of orotracheal intubation more than twice during the laryngoscopy is a defining factor of difficult intubation. This is a frequent problem in intensive care units where the rate of difficult intubation can reach 10 to 20% depending on the study [1-5] compared to the operating room (between 3 and 5%). In case of difficult intubation, the number of serious complications increases: there is a strong correlation between the number of laryngoscopies and the occurrence of serious complications [4-9]. Provider experience is a major determinant for the occurrence of these events [10, 11]: A median of 29 IOT is necessary to obtain a success rate higher than 80% for each intubation [12].

The association between a patient with organ failure, minimal physiological reserves and a high frequency of difficult intubation leads to a high rate of serious complications: between 25 to 40% of cases [2, 6, 13]. These complications can be hemodynamic: hypotension; respiratory: hypoxemia, inhalation and can even result in cardiac arrest and death of the patient (in 1.6% of cases by reference [3]). To reduce the frequency and severity of these complications, several axes of prevention have already been developed.

1) Optimization of the intubation procedure

a) Hemodynamics

Hemodynamically, the mechanisms (vasodilator effect of anesthetics, decreased venous return due to the introduction of positive intrathoracic pressure) leading to the occurrence of complications (hypotension, cardiac arrest) can be prevented through certain systematic actions: systematic vascular filling, the use of vasoactive amine in case of preexisting hypotension [14]. The use of anesthetic agents with a short duration of action and a specific pharmacodynamic profile is also recommended. Recommended sedatives include etomidate or ketamine [15]. Recommended muscle relaxants include succinylcholine or rocuronium in the presence of counter-indications [16]. These agents have the advantage of being very well tolerated hemodynamically.

b) Respiratory

Pre-oxygenation is an important step that increases the duration of apnea without hypoxemia by "saturating" the lungs with oxygen. This is done systematically before intubation in the ICU. Starting in 2006, it is recommended to use non-invasive ventilation for all hypoxemic patients [17] and to continue this non-invasive ventilation until the laryngoscopy if it has already begun [18]. The recommended duration of pre-oxygenation is 3 to 4 minutes according to the scientific societies [16] and an increase in this duration has so far shown no benefit [19]. It is recommended to use a capnogram, which enables measurement of exhaled carbon dioxide. This tool can show the intratracheal character of the intubation tube at the earliest stage [20]. It is currently recommended to systematically use a metal laryngoscope blade [21] and to ensure the presence of two providers during the intubation procedure [14]. In case of a difficult intubation, the use of intubation or difficult oxygenation algorithms is needed to make a quick decision concerning the measures and actions to be taken by doctors and paramedics. Training and knowledge of various alternative techniques are thus necessary for all staff working in intensive care.
All of these preventive measures allow for a reduction in severe complications when combined in a systematically implemented checklist. In this manner, a French team showed a decrease in severe complications (21% vs. 34% \( p = 0.03 \)) through the use of such a protocol [14]. The British anesthesiology society recommends that risk factors for difficult intubation be identified and collected in a medical file to be utilized for algorithms in function of risk; to use a checklist and capnography before intubation; to train staff regularly in alternative intubation techniques and various oxygenation devices; and to be especially vigilant with obese patients or those with high risk of difficult intubation, particularly during transfer [22, 23].

Nevertheless, all of these elements only allow for the prevention of related complications, but do not improve the percentage of successful intubations as the first laryngoscopy attempt remains the major determinant of these complications [7, 24]. It is thus essential to develop tools or techniques to improve the rate of successful intubations on the first attempt.

2) Improved intubation conditions

a) Neuromuscular blockade

Neuromuscular blockade have a critical role as they create glottis visibility conditions that allow for successful intubation in most cases. Meanwhile, their rapid onset of action and short duration of action allow for immediate intubation without facially ventilating the patient and thus reduce the risk of inhalation of gastric contents [25].

b) Expected scores

To reduce the risk of difficult intubation, there are predictors for the occurrence of difficult intubation [26]: mouth opening less than 35mm, chin-thyroid distance of less than 65mm, history of difficult intubation, Mallampati score greater than or equal to 3, radiotherapy in the cervical region. However, in the emergency context, these are hard to determine as patients are often non-cooperative. Despite the existence of specific validated scores predicting the risk in the form of an IDS score [27] or Macocha score [28], they have not been adopted in current clinical practice due to the impact of the use such scores and their unproven clinical impact.

c) Video laryngoscope

In recent years, new tools have been developed to facilitate orotracheal intubation: video laryngoscopes. Thanks to the presence of an optical fiber and a camera, these devices allow for a perfect, indirect glottal view (as defined by the Cormack and Lehane score or the POGO [29] score despite misalignment of the oro-pharyngolaryngeal axis.

Several studies have compared the video laryngoscopes on the market, but for the most part, they have only been evaluated in the operating room as part of a scheduled surgery [30-33]. These promising devices have rarely been studied in terms of emergency intubation in the ICU [4, 34-36]. The few studies that have compared the video laryngoscope with the classic Macintosh laryngoscope for intubation in the ICU did not take into account the experience of the providers [37]. A study carried out in the intensive care unit of Montpellier, monocentric and with a before and after approach, observes a lower difficult intubation rate in the video laryngoscope group (4% vs 16% \( p = 0.01 \)) [34]. Recently, an American study showed that improvement in the orotracheal intubation success rate in the first laryngoscopy correlated with a decreased rate of esophageal intubation in the video laryngoscope group [4]. Finally, a retrospective observational study carried out in the multipurpose intensive care unit at La Roche sur Yon showed an intubation failure rate for the first laryngoscopy that was greater in the Macintosh laryngoscope group when compared to the McGrath Mac video laryngoscope group (11/40 versus 0/23 \( p = 0.005 \)) with improved glottic view (Abstract presented at the SO135 SRLF January 2014) [36]. However, these studies have significant limitations (staffing, lack of randomization) and need to be confirmed with a strong, multicentric, randomized study to help confirm our hypotheses.

All these arguments allow us to formulate the hypothesis that tracheal intubation using this device would lead to a reduction in the rate of failure and possible serious complications due to a marked improvement in glottic vision during the procedure, allowing for success in the first laryngoscopy.

Our decision to evaluate the McGrath Mac video laryngoscope is based on several factors:
- standard intubation technique compared with a Macintosh laryngoscope with direct vision of the glottis, especially when the oro-pharyngolaryngeal axis is aligned.
- presence of an optical fiber with a camera in addition to a constant, indirect glottal view during the procedure guaranteeing correct intratracheal positioning of the intubation tube and a view of the glottis despite misalignment of the oro-pharyngeal-laryngeal axis.
- low cost of the reusable device as well as the disposable parts, allowing for frequent use.

B. Summary of benefits, if any, and foreseeable and known risks to the persons involved in the research

1. Benefits

Forseen individual benefit: reduction in the duration of the intubation period, standardization of the intubation procedure, limitation of the number of intubation attempts and risks of serious complications from this procedure

Forseen collective benefit: fewer serious complications from this procedure.

2. Risks

To the extent that the two tested devices (McGrath Mac video laryngoscope and Macintosh laryngoscope) are already marketed and used in current clinical practice in intensive care and the operating room, there is no foreseeable risk to persons undergoing research.

C. Statements indicate that the research will be conducted according to the protocol as well as good clinical practice

The investigator also agrees that this research will be conducted:
- In accordance with the laws and regulations in effect in France and Europe,
- In accordance with good clinical practices in terms of French and international regulations in effect.

D. Legislative and regulatory provisions

This research is included in the category of routine care research as defined by paragraph 2 of Article L. 1121-1 and Article R 1121-3 of the public health code.

E. Description of the population to be studied.

This study will focus on adult patients admitted to intensive care and requiring orotracheal intubation (for coma, respiratory distress, etc.) carried out by a doctor.

III. Research objectives

A. Primary objective of the study

Demonstrate an increase in the proportion of successful orotracheal intubations for the first laryngoscopy with the video laryngoscope in patients requiring orotracheal intubation in intensive care presenting less than 3 criteria for difficult intubation.

B. Secondary objectives

The secondary objectives are to compare between the two groups:
- Proportion of successful orotracheal intubations for all laryngoscopies
• Length of the procedure before successful orotracheal intubation
• Comparison of the Cormack score for glottal visibility
• Comparison of the POGO score for glottal visibility
• Proportion of difficult intubations (defined by a duration of more than 10 minutes and/or more than 2 failed laryngoscopy attempts).
• Comparing the use of alternative intubation techniques in 2 groups:
  • Use of a long angulated stylet
  • Recours à un dispositif supra glottique (type Fast-trach®)
  • Use of a video laryngoscope validated for difficult IOT (Airtraq®, Glydescope®)
  • Use of a fiberscope
  • Use of a trans-tracheal oxygenation device.
• Comparison of the frequency of occurrence of severe complications
  • Tooth breakage
  • Aspiration of gastric contents
  • Proportion of esophageal intubations
  • Desaturation <90%
  • Hypotension defined as PAS<90mmHg
  • Cardiac arrest
• Comparison of morbidity between the 2 groups:
  • Duration of artificial ventilation
  • Duration of ICU stay
  • Duration of hospital stay
• Mortality upon leaving the ICU
• Mortality at Day 28

IV. Research Design

A. A precise statement of the primary evaluation criteria and, if applicable, secondary evaluation criteria

1. Primary criteria

• Proportion of successful orotracheal intubations for the first laryngoscopy in the McGrath Mac video laryngoscope group (number of successful orotracheal intubations for the first laryngoscopy in the McGrath Mac laryngoscope group/number of patients included in the McGrath Mac laryngoscope group) to the proportion of successful orotracheal intubations for the first laryngoscopy in the Macintosh laryngoscope group (number of successful orotracheal intubations for the first laryngoscopy in the Macintosh laryngoscope group/number of patients included in the Macintosh laryngoscope group).

2. Secondary criteria

• Proportion of successful orotracheal intubations for all laryngoscopies
• Duration of the procedure before successful orotracheal intubation The total duration of the intubation procedure will be defined as the time between the induction of anesthesia and the confirmation of intratracheal character of the intubation tube defined by the appearance of the first inflection of the expired CO2 curve.
• Cormack glottal visibility score
• POGO glottal visibility score
• Difficult intubation
• Use of alternative intubation techniques:
  • Use of a long angulated stylet
  • Recours à un dispositif supra glottique (type Fast-trach®)
  • Use of a video laryngoscope validated for difficult IOT (Airtraq®, Glydescope®)
  • Use of a fiberscope
  • Use of a trans-tracheal oxygenation device
• Frequency of occurrence of adverse events:
• Tooth breakage
• Aspiration of gastric contents
• Proportion of esophageal intubations
• desaturation (SpO2<90%)
• hypotension defined as PAS<90mmHg
• cardiac arrest
• Comparison of morbidity:
  • duration of artificial ventilation
  • duration of ICU stay
  • duration of hospital stay
• Mortality upon leaving the ICU
• Mortality at Day 28

B. Description of the research methodology, with its schematic presentation, specifically including visits and expected examinations

1. Experimental design

Controlled, randomized, multi-centric, open study concerning the intubation procedure.

2. Progression of the study

Duration of inclusion: 12 months
Duration of study participation for a patient: 28 days
Duration of statistical analysis: 3 months
Duration of report drafting: 3 months
Total study duration: 18 months
This study will begin on April 13, 2015 and given the pace of inclusion and the number of planned inclusions within an expected 18-month course will end on October 13, 2016.

Each patient will benefit from monitoring for a maximum of 28 days between the date of inclusion and an evaluation performed at 28 days.

a) Inclusion

Information and research with regards to non-opposition to study participation will be provided by the patient or responsible party or, otherwise, by one of his/her relatives. If the information has been issued to the responsible party or a relative, the non-opposition research will also be made available to the patient as soon as his/her level of consciousness allows for it. In case of refusal to continue with the study, the patient will removed from the test and his/her medical data will be deleted. In all cases, the patient will be informed as soon as possible by the investigator and the collection of patient non-opposition will then be performed by the investigator. If the patient is not able to provide consent, and the responsible party or a relative cannot be reached, an emergency inclusion process will be carried out according to research protocol.

A follow-up table of patients to whom the study was proposed will be kept up-to-date, noting the reasons for non-inclusion and opposition to participation.

After verification of the criteria for inclusion and non-inclusion and after receiving the consent from the patient or his/her relatives or in case of an emergency procedure, the investigator will include the patient. Upon inclusion, demographic data will be collected, including characteristics and the patient's vital signs, date of birth, sex, date of ICU admission, McCabe and Knaus scores, prior chronic conditions, weight, height, index body weight, vital signs (pulse oxygen saturation, blood pressure, heart rate, respiratory rate) and the predictive criteria for difficult intubation (limited mouth opening less than 3.5 cm, chin-thyroid distance of less than 6.5 cm, Mallampati score greater than or equal to 3, decreased mobility cervical spine, obstructive sleep apnea, a history of difficult intubation) with a calculation of the Macocha score.

Randomization will then be carried out via computerized data collection (eCRF): a random group will be assigned to the patient: VL group (video laryngoscope) or LM group (direct macintosh laryngoscopy).
b) **Intubation procedure**

The intubation procedure will be subject to protocol using groups that will be broken down as follows:

1. **Patient screening and randomization**

   When a decision is made to perform an emergency orotracheal intubation on a patient, the doctor in charge of the patient will ensure compliance with the criteria of inclusion and non-inclusion and deliver the information to the patient, the responsible party or carry out the procedure based on emergency inclusion, ensuring randomization of the patient via the eCRF.

2. **Preparation for the intubation procedure, pre-oxygenation, anesthetic induction sequence**

   Pre-oxygenation will be carried out using a device of the attending physicians choice:
   - Oxygenation using an auto-inflating balloon with a one-way valve (BAVU) connected to the wall and fed by oxygen at a minimum of 15 l/min for at least 3 minutes [38, 39].
   - Oxygenation using a high concentration mask with a balloon reservoir connected to the wall and fed by oxygen at a minimum of 15 l/min for at least 3 minutes [40].
   - Oxygenation using a heavy resuscitation respirator set in noninvasive ventilation mode with 100% FiO2 for a minimum of 3 minutes.
   - Oxygenation using OptiFLOW® or a similar device with 100% FiO2 for a minimum of 3 minutes, connected to the wall and fed by oxygen at a minimum of 60 l/min.

   The induction of anesthesia will then be carried out using a sedative and a curare. The choice of molecules and their dosages will be the choice of the attending physician. Nevertheless, in accordance with recommendations both internationally [41] and in France [42]:
   - Neuromuscular first chosen unless contraindication (hyperkaliemia, allergy, medullar lesion after 24h) will be succinylcholine at dose of 1mg/kg (or rocuronium at a dose of 1mg/if antidote : Bridion© is available at dose of 16mg/kg)/
   - Two sedative options will be hypnomidate at a dose of 0.2 to 0.3 mg/kg or ketamine at a dose of 1 to 2 mg/kg.

3. **Laryngoscopy and intubation**

   The laryngoscopy will be performed using the device assigned by randomization:
   - VL Group: McGrath video laryngoscope
   - LM Group: standard Macintosh laryngoscope

   For non-expert providers concerning one of the two techniques or both techniques, theoretical courses and an apprenticeship using a dummy will be completed by each provider before participation in the MACMAN study (minimum of 5 trials on a dummy for each type of intubation will be required).

   Intubation is then performed using an intubation tube chosen by the attending physician. The balloon for this tube will be inflated and a respirator will be connected to the tube.

   If intubation during the first laryngoscopy is unsuccessful, the doctor may choose to perform a second laryngoscopy or use alternative intubation techniques. A management algorithm for difficult intubation will be utilized in the different services involved in the study.

   The doctor will choose whether or not to apply pressure on the cricoid cartilage during the intubation procedure (Sellick maneuver). Use of this maneuver will be recorded in the electronic CRF.

4. **Verification of the intratracheal character of the intubation tube and patient ventilation**

   The intratracheal character of the intubation tube should be affirmed by the observation of a capnography curve consistent over 3 respiratory cycles. The total duration of the intubation procedure will be
defined as the time between the induction of anesthesia and the confirmation of intratracheal character of the intubation tube defined by the appearance of the first inflection of the expired CO2 curve.

c) Patient follow-up

Flow Chart:

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Day 1 Inclusion</th>
<th>Day 1 Preoxygenation</th>
<th>Day 1 Intubation</th>
<th>Day 2 through 5</th>
<th>Day Release from intensive care</th>
<th>Day 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility: check eligibility criteria of the study</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-opposition research</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient characteristics</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical evaluation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Biology</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Administered treatment</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final extubation</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Alive/Deceased</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Day 1 corresponds with the beginning of the intubation procedure.

C. Description of measures taken to reduce and avoid bias

1. Random drawing

Randomization will be publicly carried out on the day of inclusion by the patient's attending physician, and will be based on two groups of patients: VL Group and LM group. Randomization will be stratified according to the health care center and the provider's experience, defined as follows:

- expert provider: intensive care physician working in the ICU for a minimum of five years, or one year if he/she has had prior training in anesthesia for a minimum period of 24 months [11].
- non-expert provider: all other cases (less than 5 years experience in the ICU and/or less than 24 months of training in anesthesia, less than 1 year in intensive care.)

It will be carried out according to a ratio 1:1 and will be carried out by blocks.

Randomization will be performed using the online CLINSIGHT software on the website: https://www.dirc-hugo-online.org/csonline/. Connection will be made using a login, a password and a study number, issued by a data-manager of the Department of Research Promotion of CHU Nantes.

The following information must be provided:
- Initial of last name
- Initial of first name
- Date of birth
- Compliance with the criteria for inclusion and non-inclusion (yes/no)
- Collection of non-opposition/emergency procedure (yes/no).

The inclusion number will be automatically assigned at randomization. A confirmation message will be sent to the person who performed the randomization and to all those concerned.

The randomization list will be created by a statistician from the Department of Research Promotion of CHU Nantes. An explanatory guide to the randomization procedure will be available online in CLINSIGHT.
2. Blind method

The trial will be conducted publicly, since it is impossible for it to be double blind because the provider is aware of the material used for intubation. However, the primary evaluation criterion is that of objective clinical evaluation: success of the procedure with confirmation of intratracheal character of the intubation tube with the analysis of the expired fraction of carbon dioxide at the end of expiration (PetCO2), thus decreasing the bias of the provider.

D. Expected duration of participation of persons and description of the timeline and duration of all periods of the test, including monitoring, if applicable

The patient monitoring period in the study will depend on its progression. The patient will be monitored until he/she leaves the ICU or, in case of prolonged hospitalization in intensive care, monitoring will continue for a maximum of 28 days.

1. Ending the participation of a research subject

Participation in the study will end in case of secondary opposition of the patient

2. Stopping part or all of the research

Interim analysis is not planned in the framework of this research. Nevertheless, concerning this study of routine care, if consensus from a scientific publication would undermine the main hypothesis, this research could be stopped early by decision of the promoter.

V. Selection and exclusion of research subjects

A. Inclusion criteria for persons who consent to research

- Patient in intensive care requiring mechanical ventilation using an intubation tube.

B. Exclusion criteria for persons who consent to research

- Counter-indication for orotracheal intubation (including unstable cervical spinal injuries)
- No delay allowing for the inclusion and randomization of the patient (including a heart attack)
- Minor (<18 years)
- Woman that is pregnant, parturient or nursing
- Hospital patient without consent and/or deprived of liberty by the justice system
- Patient under guardianship
- No Social Security
- Refusal of the responsible party or patient
- Patient participation in a research protocol whose primary criteria is based on the intubation procedure

C. Recruitment procedures

Recruitment will be done in the ICU of centers participating in the study. The study plans to include 370 patients admitted to intensive care and requiring a tracheal intubation procedure, after the provision of the informational letter and collection of non-opposition from the patient or responsible party, or through the emergency inclusion process. In the latter two cases, the non-opposition of the patient will be collected retrospectively after reading the informational letter.
VI. Procedures and treatments administered to persons who consent to research

A. Authorized treatment

Being a routine care study, all drugs commonly used for the care of ICU patients will be used according to each patient's specific needs.

B. Unauthorized treatment

Being a routine care study, no drug used in accordance with its indication is prohibited.

Safety assessment

The occurrence of undesirable effects related to patient care during this protocol will result in a declaration in the proper vigilance system (pharmacovigilance, biomonitoring, blood safety, medical device, etc ...).

VII. Statistics

A. Description of planned statistical methods, including the timing of planned interim analyses

Statistical analysis will be conducted according to a pre-established analysis plan using SAS ® 9.3 software. Analysis will be conducted according to the principle of the intent-to-treat analysis. A statistical analysis report will be produced, integrating all the elements that must be reported as recommended by the CONSORT Statement, taking into account the specificities pertaining to the fact that it is not a pharmacological trial.

Description of the inclusion samples

Patients will be described, upon inclusion, overall and in both groups, by the numbers and percentages of each modality for qualitative variables and the minimum, maximum, average, standard deviation and quartiles for quantitative variables. No statistical tests will be performed to compare the 2 groups.

Analysis samples

The analysis will be by intention-to-treat, each subject remaining in the group in which he/she was randomized, come what may.

Analysis of primary evaluation criteria

The evaluation criteria corresponds with the proportion of successful orotracheal intubations in the first laryngoscopy. This factor will be compared between the 2 groups (laryngoscope vs video laryngoscope) using a mixed logistic model that takes into account the two stratification factors (center in terms of randomness and experience of the provider in fixed effect). A sensitivity analysis will be conducted to take the Macocha score into account.

Analysis of secondary criteria

Secondary criteria will be analyzed using generalized, mixed regression models (linear or logistic depending on the type of variables). These models take into account the stratification of the randomization of the center and experience of the provider (center in terms of randomness and experience of the provider in fixed effect).

Schedule of interim analyses

No intermediary analysis is planned.
Subgroup analyses
An analysis of the subgroup of patients who were intubated without difficult intubation (after more than 2 laryngoscopies or during a procedure that lasted more than 10 minutes) will be performed.

B. Expected number of people to include in the research, and the expected number of people in each research location with a statistical justification

Taking into account that the proportion of patients successfully intubated during the first ICU laryngoscopy will be 65% in the Macintosh group [34, 43], and assuming that the use of McGrath Mac video laryngoscope will achieve a success rate of 80%, and setting an alpha risk of 5% and a beta risk to 10%, it is expected to include 185 patients per group is 370 patients in total.

C. Degree of expected statistical significance

All statistical tests will be performed with a significance level of 5%.

D. Method for taking into account missing, unused or invalid data

Given the duration of participation and that the collection of principal evaluation criteria is possible just after randomization, no missing, unused or invalid data is expected.

E. Managing changes to the plan of analysis for the initial strategy

The statistical analysis plan will be finalized with the base gel.

F. Choice of subjects to be included in the analyses

The primary analysis population is the population in intent-to-treat, corresponding to all patients randomized in the study. A sensitivity analysis on the per protocol population will be carried out. This population includes the patients that comply the most with protocol: compliance with criteria for inclusion and non-inclusion and no major protocol deviations.
VIII. Justification of the request for validation of research in routine care

In accordance with the decree of March 9th, 2007 and taking into account all the elements presented in the project, the head of research categorizes the primary objective of the project as research in routine care, since:

✔ All orotracheal intubation protocols and actions are performed as usual.
✔ The research is meant to evaluate combinations of actions, and medical strategies for prevention and diagnosis (orotracheal intubation procedure using a laryngoscope) which are common practice, that is to say, it is of professional consensus that they respect current indications. A practical survey conducted in 2013 found that 28% of doctors working in intensive care had a video laryngoscope in their service [44]. The service of La Roche Sur Yon has had a McGrath Mac video laryngoscope since November 2013 and they use it daily for the intubation of patients in intensive care.
✔ This research does not address techniques or strategies that are either innovative or outdated.
✔ The research focuses on the comparison of two medical strategies, neither of which can, in the current state of knowledge, be considered superior to the other in terms of safety and efficiency.
✔ As stated in the project, the protocol involves risks and monitoring constraints considered negligible compared to the usual care of these patients.
✔ Finally, the specific terms used in the research should reduce the risks (through enhanced protocol in the orotracheal intubation procedure) and represent significant constraints for the research subject (Article R 1121-3 of the public health code (CSP), Decree No 2006-477 of April 26th, 2006).

The head of research will thus submit, before the implementation of any research, for favorable opinion and confirmation of the qualification of the research, the study protocol to the Angers Patient Protection Committee pursuant to Article L 1121-1 of the public health code (CSP) resulting from laws 2004-806 of August 9th, 2004 and No. 2006-450 of 18 April 18th, 2006 concerning public health policy.
IX. Right of access to data and source documents

1. Data access

Medical data for each patient can only be forwarded to the affiliated organization of the person responsible for research or any person duly authorized by him in conditions ensuring their confidentiality.

2. Source documents

If necessary, the affiliated organization of the person responsible may request direct access to medical records for verification of procedures and/or research data without violating the confidentiality and to the extent permitted by laws and regulations.

3. Data confidentiality

People with direct access will take all necessary precautions to ensure the confidentiality of information relating to involved persons, in particular with regards to their identity and the results obtained. These people, along with the investigators themselves, are subject to professional secrecy (under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code).

During the research or upon its completion, the data collected concerning participants and transmitted by the individuals involved will be anonymized. It must under no circumstances include full names of the persons concerned or their addresses. Only the first letter of the subject's first and last name will be recorded, along with a unique encrypted number for the study indicating the order of inclusion of subjects.

X. Quality assurance

Quality control will be carried out by Research Clinic Associates of the Center of Clinical Research for CHD Vendée, mandated by the head of the research institution. The nature and frequency of monitoring will be established according to scheduled monitoring/risk established. Throughout the study, during monitoring visits planned with the investigator, the ARC will control:

- The data collected during the study
- Non-opposition of responsible parties and all patients involved

As such, the investigator agrees to make available to the ARC during its monitoring visits

- The medical records of patients
- Data collection files

The monitoring carried out by the ARC of the CRC will assess:

- The protection of persons
- The reliability of the data with regards to source documents
- The conformity of the test with the protocol, Good Clinical Practices and the applicable legislation on biomedical research

After this quality control, a monitoring report will be prepared by the ARC and delivered to the principal investigator who will adopt directives based on the report conclusions.

XI. Ethical evaluations and terms and conditions for the protection of persons

A. The Committee for the Protection of Persons

Before the implementation of research, the head research institution will submit the project to the West CPP and will provide all the necessary information (research protocol, information notice for the patient and relatives). The trials will start when the CHD Vendée has been notified of CPP issued approval.
B. **Substantial changes**

Any substantial change to the protocol of the study should be provided to the Committee for the Protection of Persons to verify that the proposed changes do not alter at any time the guarantees given to individuals who lend themselves to the research.

The modified protocol will be an updated, dated version.

C. **Informational and not-opposition letter**

If the patient is unable to speak because of his clinical condition at the time of inclusion, the responsible party or, by default, his/her relatives will be fully and faithfully informed, in understandable terms, of the objectives and constraints of the study, potential risks, monitoring measures and necessary safeguards, of their right to refuse involvement of the patient in the study and the possibility of withdrawal at any time.

All of this information is contained on an informational notice, a copy of which will be given to the responsible party or the patient's relative while the investigator retains the original.

After a period of reflection and after ensuring the proper understanding of the form, the investigator will collect non-opposition from the responsible party.

If the patient is not deemed fit to receive information and if no responsible party or relative can be reached, an emergency patient inclusion procedure will be available to investigators. The information will be issued and the non-opposition collected from the patient as soon as he is deemed fit.

D. **Definition of the exclusion period**

No exclusion period is expected for this research.

E. **Care related to the research**

The care of patients included in this study was modeled on the care typically recommended as part of an orotracheal intubation procedure. No additional exams will be conducted for this study.

F. **Justification for patient inclusion due to an emergency protocol**

This research falls within the framework of Article L. 1122-1-2 of the Public Health Code. Indeed, the inclusion criteria imply the inclusion of patients that may have impaired consciousness and/or vital distress that does not allow for the issuance of information. The patient will be in no condition to give his non-opposition to participate in the study. Pursuant to Article L. 1122-1-2 of the Public Health Code, the information and the lack of opposition from the responsible party or, by default, a relative, will therefore be sought through all available means of the associated investigator at the time of patient admission.

Information and the absence of opposition from the patient will be collected as soon as possible.

XII. **Processing of data and storage of documents and data**

A. **Observation file**

An electronic collection of data will be used as part of this study. This electronic report file will be set up in each center. It only requires an Internet connection and a browser. A help document for the use of this tool will be provided to investigators.

Data consistency control tests will be included in electronic format. An audit function is integrated into the electronic file and can track any changes in the study data. This function also allows for clear identification of the person who made the change and the date. A justification can be optionally integrated in the comments.

B. **Producing and entering data**

Data entry is performed on an electronic storage system via a web browser.
C. French Data Protection Authority (CNIL)

A notice concerning the implementation of data processing necessary for the realization of the study will be requested from the advisory committee for the processing of research information in the health sector (CCTIRS) and will be followed by an authorization request for the French Data Protection Authority (CNIL) on the processing of personal data for the purpose of clinical research.

D. Archiving

The following documents will be archived under the name of the study in the facilities of the multipurpose ICU of CHD Vendée until the end of the period of practical utility.

These documents are as follows:
- Protocols and annexes, possible amendments,
- Information notices,
- Individual data (authenticated copies of raw data)
- Follow-up documents,
- Statistical analyses,
- Final report of the study.

At the end of the period of practical use, all documents to be archived, as defined in the classification process and document archiving related to CHD Vendée biomedical research, will be transferred to the archive site (Clinical Research Center CHD Vendée) and will be placed under the responsibility of the institution responsible for research for 15 years following the end of the study in accordance with the institutional practices.

No displacement or destruction can occur without the consent of the institution responsible for the research. After 15 years, the institution responsible for the research will be consulted for destruction. All data, documents and reports may be subject to audit or inspection.

XIII. Financing and insurance

A. Study budget

Being a study in routine health care practices, it is not intended for medical time funding. The expected study duration is 18 months (recruitment over 12 months) for the 370 patients included. Thus, the costs of this research are as follows:

- ARC monitoring time for monitoring visits (8 visits/centers + closure): €16,000
- Travel expenses for ARC monitoring for monitoring visits (introductory and final visits, 2 visits/year/center): €6,250
- Data management: Data management time for the creation of electronic observation files and monitoring of data quality: €5,310
- Stationary for informational and non-opposition statements for the patients or their relatives, bedside monitoring sheets: €500
- Purchase of McGrath laryngoscopes and consumables (1 device per service for 7 services, 1 extra battery and 50 disposable blades): €12,576
- Meeting: €2,000
- Total: €42,636.

XIV. Insurance

To the extent that the research is well qualified for Research in Routine Care by the requested CPP, which means no additional risk related to the study, the insurance used will be that of the institution responsible for the care (Article L. 1142-2).
XV. Study feasibility

- The CHD Vendée ICU admits more than 1,000 patients per year, 60% of which are ventilated. During a practice survey conducted in the service and presented to the 2014 Congress of the French Society of Intensive Care [36], 63 patients were included in a period of 6 months (10 patients per month). In reporting these figures to the 7 centers participating in the MACMAN study, the inclusion of 4 patients per center per month seems quite reasonable.
- Under the direction of Dr. Jean Reignier, the principal investigation center recently conducted a large-scale clinical trial. This study, with the acronym NUTRIREA-1 (NCT01137487), was designed to assess the value of the general measurement of gastric residue in critically ill, mechanically ventilated patients during enteral nutrition. This study included 452 patients and was published in a journal with a high "impact factor", JAMA.
- The bio-statistic and data management teams involved in the MACMAN study are part of a large Western network (biostatistique_datamanagement_methodologie) guaranteeing the quality and accuracy of data collected and statistical analysis.

XVI. Rules of publication

Communications and scientific reports for this study will be carried out under the supervision of the coordinating investigator of the study with the consent of the responsible investigators. The co-authors of the report and publications will be the investigators and clinicians involved, in proportion to their contribution to the study, as well as the biostatistician and research associates. The rules of publication will follow international recommendations. The study will be recorded on a freely accessible website (Clinical Trial) before the 1st patient is included in this study.
XVII. Scientific literature and pertinent data will be used as a reference for the research


31. Walker, L., W. Brampton, and M. Halai, Randomized controlled trial of intubation with the McGrathw Series 5 videolaryngoscope by inexperienced anaesthetists.
33. Ng, I., et al., A randomised controlled trial comparing the McGrath(®) videolaryngoscope with the straight blade laryngoscope when used in adult patients with potential difficult airways.
XVIII. List of annexes

Annex 1

Informational letter for the family, close acquaintances or the designated responsible party

CHD Vendée MACMAN

Comparison of McGrath Mac video laryngoscope and Macintosh laryngoscope for intubation in the ICU.
Randomized study

Institution responsible for research: Vendée Departmental Hospital
Coordinating investigator: Dr. Jean-Baptiste Lascarrou
Record No.: 2014-A00674-43
Favorable opinion from the Committee of the Protection of Persons West II:
7/15/14

Dear Sir/Madam,

One of your relatives is currently hospitalized in the intensive care unit of .............................................................. and his/her physician, Dr. ... .............................. is proposing the participation of your relative in research intended to evaluate routine care. Before making a decision, it is important that you carefully read these pages, which will provide you with the necessary information concerning different aspects of this research. Feel free to ask the doctor any questions that you may have.

Why is this research being conducted?

Your loved one is currently hospitalized in intensive care due to a disease or incident and requires mechanical ventilation. A tracheal tube will be placed in his trachea in order to connect the lungs to an artificial ventilation machine.

The equipment used to perform the intubation is a laryngoscope, as it allows the physician to see the larynx, vocal cords and trachea. In the operating room, the standard equipment is a conventional laryngoscope called "Macintosh" that allows a direct view of the trachea.

New laryngoscopes, known as video laryngoscopes, have existed for several years and allow for intubation using a video camera. Several studies have proven the effectiveness of these video laryngoscopes in patients undergoing general anesthesia in the operating room. However, few studies have proven the value of these video laryngoscopes in intubated patients in emergency situations, specifically in the ICU. Therefore, we hope to prove that these video laryngoscopes can improve the intubation procedure in relation to the Macintosh laryngoscope, thereby limiting the risk of complications from this procedure.

These video laryngoscopes are commonly used in the ICU Roche sur Yon and several departments involved in the MACMAN study. Nevertheless, the benefit of their systematic use compared to a Macintosh laryngoscope has not been shown and is the subject of the MACMAN study.
**What is the overall conduct of this study?**

A random drawing will determine the care of your loved one: either using a Mac Grath video laryngoscope or a Macintosh laryngoscope. There are no additional constraints with regards to the standard care of patients with this pathology. In any case, your loved one will benefit from all modern diagnostic and therapeutic methods currently available. All physicians participating in this research have mastered this technical process and know how to manage potential complications.

The duration of study participation corresponds to the duration of hospitalization in intensive care. The benefit to your loved one is minimizing the number of intubation attempts, thereby limiting the risk of complications. The health of your loved one will be monitored for 28 days after his/her inclusion in the study via telephone interview. In case your loved one cannot be reached, we will contact his/her attending physician.

His/her participation in this study may be interrupted for medical reasons and you or your loved one can at any time exercise your right to withdraw from this research.

Moreover, the patient's non-opposition will be collected as soon as his/her condition allows. If ultimately, he/she does not want to participate, he/she will be removed from the study and the data will be deleted.

**Will be additional charges for the patient?**

The participation of your loved one this research will result in no extra cost beyond that of his/her usual care.

**What are the patient's rights?**

- **Professional secrecy**
  Staff involved in the research is subject to professional secrecy, as is the attending physician of your loved one.

- **Access to data regarding your loved one - Data processing**
  As part of this research, data processing of your loved one's personal data will be implemented: it will analyze the results of research and fulfill the purpose of the research. For this, the medical data regarding your loved one will be forwarded to the institution responsible for research (CHD Vendée) or to persons or companies acting on its behalf. This data will be identified by a code number and the initials of your loved one.
  In accordance with provisions from the French Data Protection Authority (law relating to computers, files and freedoms, modified on January 6th, 1978), you have a right to access and rectification. You also have the right to object to the transmission of data covered by professional secrecy which may be processed and used as part of this research.
  Such rights are exercised by the investigating physician who is aware of your loved one's identity and is caring for him/her as part of the research.

- **Access to global research results**
  At the end of the research, and at the request of your loved one, he/she will be informed by the investigating physician of the overall results of this research (as soon as they are available).

**Regulatory framework**

This research has received the approval of the Committee for the Protection of Persons WEST II - ANGERS on 07/15/14 pursuant to Article L. 1121-1 of the public health code.

The coordinating investigator of the study is Dr. Jean Baptiste LASCARROU, Multipurpose Intensive Care Unit of the Departmental Hospital of Vendée in La Roche Sur Yon (Tel 02 51 44 62
12). The institution responsible for research is the Vendée Departmental Hospital, CHD located in La Roche Sur Yon, Les Oudairies 85925 La ROCHE SUR YON Cedex 9.

Do not hesitate to ask your loved one's attending physician for answers to any questions that you may have.
Annex 2

Instructions for emergency inclusion procedure in the absence of a responsible party or a loved one

CHD Vendée MACMAN

Version 4 of 02/17/2015

Comparison of McGrath and Macintosh laryngoscope for intubation in the ICU
Randomized study
MACMAN Study

Statement of the study's investigating physicians

I, Dr. .................................., investigator in the MACMAN study, have examined the patient Mr/Mrs/Miss (Last, first name) .................. in order to assess his/her overall condition and ability to sign the present non-opposition form.

Given his/her state (state why it is impossible for the patient to sign): ......................................................... .. the patient seems unable at present to understand information concerning the study for which we propose his/her participation and to personally confirm non-opposition. There is no reason to believe that the patient refuses to take part in this study.

I agree, in accordance with the law (Article L. 1122-1 of the Public Health Code), to ensure that non-opposition is collected from the patient as soon as possible.

Full name of study doctor: .........................
Date:.........................
Signature:.........................
Annex 3

Informational letter for the patient before intubation

CHD Vendée MACMAN

Version 5 of 02/20/15

Comparison of McGrath and Macintosh laryngoscope for intubation in the ICU.
Randomized study
MACMAN Study

Institution responsible for research: Vendée Departmental Hospital
Coordinating investigator: Dr. Jean-Baptiste Lascarrou
Record No.: 2014-A00674-43
Favorable opinion from the Committee of the Protection of Persons West II: 7/15/14

Patient Name:…………………… Date of birth:……………………

Dear Sir/Madam,
you are currently hospitalized in the intensive care unit …………………………….
and your doctor, Dr. ……………………………. … invites you to participate in research intended to assess current care. Before making a decision, it is important that you carefully read these pages, which will provide you with the necessary information concerning different aspects of this research. Feel free to ask your doctor any questions that you may have.

**Why is this research being conducted?**

You are currently hospitalized in the intensive care due to a disease or incident and require mechanical ventilation. A tracheal tube will be placed in your trachea in order to connect the lungs to an artificial ventilation machine.

The equipment used to perform the intubation is a laryngoscope, as it allows the physician to see the larynx, vocal cords and trachea. In the operating room, the standard equipment is a conventional laryngoscope called "Macintosh" that allows a direct view of the trachea. However, in some patients, the anatomy does not allow for intubation using the Macintosh laryngoscope because the trachea is not visible: intubation is thus difficult and the risk complications for the patient increases.

New laryngoscopes, known as video laryngoscopes, have existed for several years and allow for intubation using a video camera: this video camera, in theory, allows for intubation in difficult cases. Several studies have proven the effectiveness of these video laryngoscopes in patients undergoing general anesthesia in the operating room. However, few studies have proven the value of these video laryngoscopes in intubated patients in emergency situations, specifically in the ICU. Therefore, we hope to prove that these video laryngoscopes can improve the intubation procedure in relation to the Macintosh laryngoscope, thereby limiting the risk of complications from this procedure.

These video laryngoscopes are commonly used in the ICU Roche sur Yon and several departments involved in the MACMAN study. Nevertheless, the benefit of their systematic use compared to a Macintosh laryngoscope has not been shown and is the subject of the MACMAN study.
What is the overall conduct of this study?

The study aims to evaluate intubation via two different mechanisms: Mac Grath video laryngoscope or Macintosh laryngoscope.

A random drawing will determine your care during intubation: either using a Mac Grath videolaryngoscope or using the Macintosh laryngoscope. There are no additional constraints with regards to the standard care of patients with this pathology. In any case, you will benefit from all modern diagnostic and therapeutic methods currently available. All physicians participating in this research have mastered this technical process and know how to manage potential complications.

The duration of study participation corresponds to the duration of hospitalization in intensive care. The expected benefit is minimizing the number of intubation attempts, thereby limiting the risk of complications. Your health will be monitored for 28 days after your inclusion in the study via telephone interview. In case you cannot be reached, we will contact your attending physician.

Should a serious accident occur while using the technique, the doctor may decide not to proceed.

You are free to accept or refuse to continue to participate in this study. If you change your mind later on, you can discontinue participation without prejudice as to the quality of your medical care, in accordance with current knowledge.

Will there be additional costs?

Your participation in this research will result in no additional cost beyond that of your usual care.

What are your rights?

- **Professional secrecy**
  Staff involved in the research is subject to professional secrecy, as is your attending physician.

- **Access to your data - Data processing**
  As part of this research, data processing of your personal data will be implemented: it will analyze the results of research and fulfill the purpose of the research.
  For this, the medical data regarding your care will be forwarded to the institution responsible for research (CHD Vendée) or to persons or companies acting on its behalf. This data will be identified by a code number and your initials.
  In accordance with provisions from the French Data Protection Authority (law relating to computers, files and freedoms, modified on January 6th, 1978), you have a right to access and rectification. You also have the right to object to the transmission of data covered by professional secrecy which may be used as part of this research and be processed.
  Such rights should be exercised with the investigating physician who is aware of your identity and monitors you during the research.

- **Access to global research results**
  At the end of research, and at your request, you will be informed by the the investigating physician of the overall results of this research (as soon as they are available).

Regulatory framework

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12). The institution responsible for research is the Vendée Departmental Hospital, CHD located in La Roche Sur Yon, Les Oudairies 85925 La ROCHE SUR YON Cedex 9. Do not hesitate to ask your attending physician for answers to any questions that you may have.

Acknowledgements
Dear Sir/Madam,

Due to the severity of your condition and the medical urgency, we were unable to ask for your prior consent and you were included in this research on........................... to assess current routine care.

According to the law (Art. L1122-1-2 of the Public Health Code), it is with the responsible party that you designated or your relative if that person was present at the time of care that non-opposition was collected for your participation in this research. In the absence of the responsible party or one of your relatives, in a medical emergency, the law allows us to include you in this study without prior consent.

Thus, you are currently hospitalized in the intensive care unit of ................................................................................................... and your doctor, Dr. .......................................... invites you to participate in research to assess routine care. Now you are able to understand and express your will. If you do not object, you will continue participation in this research, which is completely voluntary and which solely constitutes the provision of your health data up until your release from the ICU; you have the right to refuse to participate. In this case, you will continue to benefit from the highest quality medical care, according to current knowledge. It is important that you carefully read these pages, which will provide you with the necessary information concerning different aspects of this research. Feel free to ask the doctor any questions that you may have.

**Why is this research being conducted?**

You are currently hospitalized in the intensive care due to a disease or incident and require mechanical ventilation. A tracheal tube was placed in your trachea in order to connect the lungs to an artificial ventilation machine.

The equipment used to perform the intubation is a laryngoscope, as it allows the physician to see the larynx, vocal cords and trachea. In the operating room, the standard equipment is a conventional laryngoscope called "Macintosh" that allows a direct view of the trachea. However, in some patients, the anatomy does not allow for intubation using the Macintosh laryngoscope because the trachea is not visible: intubation is thus difficult and the risk complications for the patient increases.
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Therefore, we hope to prove that these video laryngoscopes can improve the intubation procedure in relation to the Macintosh laryngoscope, thereby limiting the risk of complications from this procedure. These video laryngoscopes are commonly used in the ICU Roche sur Yon and several departments involved in the MACMAN study. Nevertheless, the benefit of their systematic use compared to a Macintosh laryngoscope has not been shown and is the subject of the MACMAN study.

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A random drawing will determine your care during intubation: either using a Mac Grath videolaryngoscope or using the Macintosh laryngoscope. There are no additional constraints with regards to the standard care of patients with this pathology. In any case, you will benefit from all modern diagnostic and therapeutic methods currently available.

The duration of study participation corresponds to the duration of hospitalization in intensive care. The expected benefit is minimizing the number of intubation attempts, thereby limiting the risk of complications. Your health will be monitored for 28 days after your inclusion in the study via telephone interview. In case you cannot be reached, we will contact your attending physician.

If a serious accident occurred during the use of the technique, the doctor was at liberty to discontinue this technique.

You are free to accept or refuse to continue to participate in this study. If you change your mind later on, you can discontinue participation without prejudice as to the quality of your medical care, in accordance with current knowledge.

**Will there be additional costs?**

Your participation in this research will result in no additional cost beyond that of your usual care.

**What are your rights?**

- **Professional secrecy**
  Staff involved in the research is subject to professional secrecy, as is your attending physician.

- **Access to your data - Data processing**
  As part of this research, data processing of your personal data will be implemented: it will analyze the results of research and fulfill the purpose of the research.
  For this, the medical data regarding your care will be forwarded to the institution responsible for research (CHD Vendée) or to persons or companies acting on its behalf. This data will be identified by a code number and your initials.
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  Such rights should be exercised with the investigating physician who is aware of your identity and
monitors you during the research.

- **Access to global research results**
  
  At the end of research, and at your request, you will be informed by the investigating physician of the overall results of this research (as soon as they are available).

**Regulatory framework**

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Do not hesitate to ask your attending physician for answers to any questions that you may have.

Acknowledgements
### Annex 5: MACOCHA score

<table>
<thead>
<tr>
<th>Points</th>
<th>Risk factors related to the patient</th>
<th>Factors related to pathology</th>
<th>Factors related to the provider</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>- Mallampati score III or IV</td>
<td>- Coma</td>
<td>- No anesthetist</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>- Obstructive sleep apnea syndrome</td>
<td>- Severe hypoxemia (&lt;80%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>- Decreased mobility of the cervical spine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>- Limitation of mouth opening &lt;3 cm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Annex 5: POGO score

**Figure 1:** percentage of glottal opening score (POGO). It is represented by the visible portion of glottis. This score ranges from 0%, when no structure of the glottis is visible, to 100%, when a the full glottis is visible, including the anterior commissure.

### Annex 6: Cormack score