INFORMATION NOTE

Effect of endotracheal tube plus STYLET versus endotracheal tube alone on successful first-attempt tracheal intubation among critically ill patients: The multicenter randomised STYLETO study protocol

STYLETO Study

Research promotor: *Montpellier University Hospital*

Main investigator: *Pr Samir Jaber*

Madam, Sir,

Your doctor offers you the opportunity to participate in a research project promoted by Montpellier University Hospital. Before making a decision, it is important that you read these pages carefully as they will provide you with the necessary information concerning the different aspects of this research. Don't hesitate to ask your doctor any questions you may have.

Your participation is entirely voluntary. If you do not wish to take part in this research, you will continue to benefit from the best possible medical care in accordance with current knowledge.

WHY THIS RESEARCH?

You are going to be "intubated", which means that you will be put on an intubation tube ("tubing") to connect you to a ventilator to help you breathe.
Sometimes this tube can be difficult to put in place, and can be complicated by a drop in your blood oxygen level.
A "Stylet" can be added to the tube to make it more rigid to make it easier to insert. The addition of this stylet is intended to reduce the difficulty of intubation.
Both methods (with or without a stylet) are performed in routine practice.
To date, no study has evaluated the impact of the addition of a stylet on the difficulty of intubation and its complications.

WHAT IS THE OBJECTIVE OF THIS RESEARCH?

The objective of this study is to determine whether the addition of a stylet to the intubating tube leads to more frequent successful intubation on the first attempt, i.e. to increase the success rate on the first attempt.

HOW IS THIS RESEARCH GOING TO UNFOLD?

This is a so-called randomized (i.e. by drawing lots) comparative study comparing 2 groups: a control group "intubating tube alone" and an intervention group "addition of a stylet to the intubating tube" which will be conducted in 30 centres. 1040 patients will be recruited over a period of 18 months.
After the draw, you will be "intubated" either with an intubating tube alone or with an intubating tube pre-formed by adding a stylet inside.

WHO CAN PARTICIPATE?

Any critically ill patient who needs to be intubated can participate. The latter must be of legal age, must be a beneficiary or be affiliated to a social security scheme.

WHAT YOU WILL BE ASKED?

You will be treated according to the recommendations of good practice, just like any other critically ill patient. You will be monitored until you are discharged from the hospital.
There are no special restrictions.

WHAT ARE THE EXPECTED BENEFITS?

This clinical study has a direct benefit for the patients included. Its aim is to reduce the difficulty of intubation and therefore the complications of intubation.

WHAT ARE THE EXPECTED INCONVENIENTS?

There is no additional risk compared to any intubation performed in critically ill patients.
The addition of a stylet may in exceptional cases, when incorrectly positioned, lead to tracheal injury. Every precaution will be taken to ensure that the stylet is correctly positioned.

WHAT ARE THE POSSIBLE MEDICAL ALTERNATIVES?

An intubating tube is mandatory for intubation. The only two modalities are the presence of an intubating tube alone or with a stylet inside.

WHAT ARE THE MODALITIES OF MANAGEMENT RELATED TO THE STUDY?

Once the intubating tube is in place, no further procedures will be performed. You will be monitored throughout your stay in the intensive care unit and then in hospital.
The end of the search, premature discontinuation or exclusion, does not lead to any particular management modalities.
Participation in this research will not generate any additional costs compared to those you would have for the usual follow-up of this disease.

WHAT ARE YOUR RIGHTS?

Your doctor must provide you with all the necessary explanations concerning this research. If you wish to withdraw at any time, for whatever reason, you will continue to benefit from medical monitoring and this will not affect your future monitoring.
In accordance with the regulations, you must be a beneficiary of a social protection scheme in order to participate in research involving humans.

In accordance with Article L.1111-6 of the Public Health Code, you may designate a trusted person who may be a relative, a close friend or your treating physician and who will be consulted in the event that you are unable to express your wishes and receive the information necessary for this purpose. This person is accountable for your wishes. Her testimony prevails over any other testimony. This designation is made in writing and co-signed by the designated person. It may be revised and revoked at any time.
If you wish, your trusted person can accompany you in your steps and attend medical interviews in order to help you in your decisions.

As part of the research in which the Montpellier University Hospital offers you the opportunity to take part, your personal data will be processed in order to analyse the results of the research with regard to the objective of the research that has been presented to you.
The responsible of this treatment is the *Montpellier University Hospital.*

The study investigator and any other study personnel bound by professional secrecy and under the responsibility of the physician in charge of your treatment will collect medical data about you. This information, called "Personal Information", will be recorded on forms, called case report forms, provided by the sponsor. Only the information strictly necessary for the treatment and the purpose of the research

will be collected on a secure database and then kept at the end of the research, under the responsibility of Prof. Samir Jaber for 15 months.
In order to ensure the confidentiality of your personal information, neither your name nor any other information that would allow you to be directly identified will be entered in the observation notebook or in any other file that the study's medical investigator will provide to the research sponsor or to persons or companies acting on his behalf, in France or abroad.

This data will be identified by a code (inclusion number and initials). The code is used so that the study physician can identify you if necessary. This data may also be transmitted to the French health authorities under conditions that ensure its confidentiality.

In accordance with the provisions of the law on data processing, data files and individual liberties (law no. 78-17 of 6 January 1978 on data processing, data files and individual liberties as amended by law no. 2018-493 of 20 June 2018 on the protection of personal data) and the general regulations on data protection (EU regulation 2016/679), you have the right to access, rectify, delete or limit the information collected about you in the context of this processing.
In certain cases, you may also refuse the collection of your data and object to certain types of data processing being carried out. You also have the right to object to the transmission of data covered by professional secrecy that may be used in the course of such research and processing.
You may also have direct access, or through the intermediary of the doctor of your choice, to all your medical data pursuant to the provisions of Article L1111-7 of the Public Health Code.

You may withdraw your consent to the collection of your data for this processing at any time. Where applicable, in accordance with article L.1122-1-1 of the Public Health Code, the data concerning you that will have been collected prior to your withdrawal of consent may not be deleted and may continue to be processed under the conditions provided for by the research.

Finally, you may request that the personal information collected be provided to you or a third party in digital format (right of portability).

Your rights mentioned above are exercised with the doctor who is following you in the research and who knows your identity.

If you have any further questions about the collection or use of your personal information or the rights associated with this information, you can contact the Data Protection Officer of Montpellier University Hospital (Tel: 04 67 33 72 71) or the investigating physician at your centre, Dr. Samir Jaber.

If, despite the measures put in place by the sponsor, you feel that your rights are not being respected, you may file a complaint with the competent data protection supervisory authority in France, the Commission Nationale de l'Informatique et des Libertés (CNIL).

If the data controller wishes to further process your personal data for a purpose other than that for which your personal data were collected, you will be informed in advance about this other purpose, the length of time your data will be kept, and any other relevant information to ensure fair and transparent processing.

Searches mentioned in 1° of article L. 1121-1 relating to the products mentioned in article L. 5311-1 :

We inform you that you will be registered in the national file of persons who lend themselves to research provided for in Article L.1121-16 of the Public Health Code. You have the possibility to check with the Minister

in charge of Health the accuracy of the data concerning you in this file and the destruction of the data at the end of the period provided for by law.

In accordance with the law n°2012-300 of 5 March 2012 relating to research involving the human person :

- this research has obtained a favourable opinion from the Committee for the Protection of Persons of name of the CPP (category 2)

- The promoter of this research, the CHU de Montpellier (Centre Administratif André Bénech. 191, avenue du Doyen Gaston Giraud, 34295 Montpellier cedex 5), has taken out a civil liability insurance policy with Newline Syndicate 1218 at Lloyd's. (Category 2)

- persons who have suffered harm as a result of participation in research involving humans may assert their rights before regional conciliation and medical injury compensation commissions

- When this search is completed, you will be kept personally informed of the overall results by your doctor as soon as they are available, if you wish.

After reading this information note, do not hesitate to ask your doctor any questions you may have. After a period of reflection, if you agree to participate in this research, you must complete and sign the consent to participate form. A copy of the complete document will be given to you.

Thank you.

CONSENT FORM

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I .....*(name, surname)* certify that I have read and understood the briefing note provided to me.

I had the opportunity to ask all the questions I wished to the Pr/Dr ..... *(name, surname)* who explained to me the nature, objectives, potential risks and constraints associated with my participation in this research.

I am aware of the possibility that I may interrupt my participation in this research at any time without having to justify my decision and I will do my best to inform the doctor who is following me in the research. This will of course not affect the quality of subsequent care.

I have been assured that the decisions that are necessary for my health will be taken at any time, in accordance with the current state of medical knowledge.

I am aware that this research has received a favourable opinion from the Committee for the Protection of Individuals (category 2) and has obtained compliance with the General Data Protection Regulations.

The promoter of the research, the CHU de Montpellier (Centre Administratif André Bénech. 191, avenue du Doyen Gaston Giraud, 34295 Montpellier cedex 5), has taken out civil liability insurance with Newline Syndicate 1218 at Lloyd's (Category 2).

I accept that the persons collaborating in this research or mandated by the promoter, as well as possibly the representative of the Health Authorities, have access to the information in the strictest respect of confidentiality.

I accept that the data recorded in the course of this research may be subject to computerised processing under the responsibility of the promoter.

I have noted that, in accordance with the provisions of the law relating to data processing, files and freedoms, I have the right to access, rectify, limit the processing of my data and make a complaint to the Commission Nationale de l'Informatique et des Libertés (CNIL): https://www.cnil.fr/. I also have the right to oppose the transmission of data covered by professional secrecy

Having had sufficient time for reflection before making my decision, I freely and voluntarily agree to participate in the research "Determination of optimal spontaneous ventilation testing during mechanical ventilation withdrawal: a physiological cross-over study in the resuscitation patient and perioperative medicine".

I may at any time ask for further information from the doctor who proposed me to participate in this research, telephone number:

Done in .....the ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

Done in .....the ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

Patient signature :

Physician signature :