INFORMATION NOTE

Non-invasive ventilation vs oxygen therapy after extubation in patients with obesity in intensive care units:
The multicentre randomised EXTUB-OBESE study protocol
EXTUB-OBESE Study

Research promoter: Montpellier University Hospital
Main investigator: Dr Audrey DE JONG

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.

WHAT IS THE OBJECTIVE OF THIS RESEARCH?

You have been intubated and put on invasive mechanical ventilation. The objective of the research is to study the best method of oxygenation following the removal of the tube connecting it to the ventilator (so-called extubation maneuver). Following extubation in intensive care, the main risk is the development of acute respiratory failure, which occurs in 10 to 20% of cases. This acute respiratory failure can lead to reintubation. The objective is thus to show that the addition of non-invasive ventilation sessions following extubation can prevent the onset of acute respiratory failure and therefore reduce the need for reintubation. The use of non-invasive ventilation would be particularly appropriate in patients with a body mass index ≥ 30 kg/m², defining "obesity", due to their morphological characteristics. Between sessions of non-invasive ventilation, two oxygen therapy methods will also be compared: so-called "standard" oxygen therapy by Venturi mask versus high-flow nasal oxygen therapy.

WHAT IS THE METHODOLOGY OF THE STUDY?

This is a therapeutic trial that will be conducted in around 40 healthcare establishments in France where 1,000 patients will be recruited over a period of 3 years. As part of this project, a computer draw (this is called randomization) will be performed to determine whether or not you will receive non-invasive ventilation in addition to the oxygen therapy following extubation. If you receive non-invasive ventilation, it will be administered in sessions of 30 minutes to 1 hour every 3 to 6 hours. If you do not receive non-invasive ventilation, you will be treated according to good practice recommendations. The management of your illness will thus be the same regardless of whether or not non-invasive ventilation is administered. The oxygen administered continuously or between sessions of non-invasive ventilation will be administered in two ways (second randomization): so-called "standard" oxygen therapy by mask or high-flow nasal oxygen therapy.

WHAT IS THE MANAGEMENT AND FOLLOWING?

If you agree that you continue the study, you will be followed for the duration of your stay in intensive care. You will receive adjuvant treatment by non-invasive ventilation or not in addition to the specific therapeutic management provided by the doctor.
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Your state of health and laboratory parameters will be monitored throughout your stay in intensive care and in hospital.

WHAT ARE THE EXPECTED BENEFITS?

Regardless of the group, this study allows you to have close monitoring by the healthcare team and optimal management of the disease.

If you are included in the so-called “experimental group (non-invasive ventilation + high-flow nasal oxygen therapy or standard oxygenation), the advantage that you could expect by participating in this study is a reduction in the work of breathing and therefore a reduction in blood pressure. risk of onset of acute respiratory failure post extubation. Conversely, if you do not have treatment with non-invasive ventilation, you will have treatment with high-flow nasal oxygen therapy or standard oxygenation, both of which are used in routine practice.

WHAT ARE THE EXPECTED INCONVENIENTS?

Insofar as the devices used (standard oxygen therapy, high-flow nasal oxygen therapy or non-invasive ventilation) are already marketed, placed on the market and used in routine clinical practice, and insofar as these devices have shown very satisfactory results in In terms of oxygenation, the use of these devices does not seem to be able to generate a significant risk during this protocol. The main risk remains the discomfort associated with the device.

WHAT ARE THE POSSIBLE MEDICAL ALTERNATIVES?

Following extubation in intensive care, the need for reintubation following the onset of acute respiratory failure occurs in 10 to 20% of cases. In order to prevent this reintubation, we will study the systematic use of non-invasive ventilation, without waiting for acute respiratory failure to appear. Between the "preventive" sessions of non-invasive ventilation, oxygen will be administered in two possible ways: either in a so-called "standard" way through a mask, or with high-flow nasal oxygen therapy, which could also make it possible to reduce episodes of acute respiratory failure and therefore reintubation. If you do not want to continue participating, you will have "standard" oxygen at all times, which is the usual treatment following extubation of intensive care patients.

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 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 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 Dr. Audrey DE JONG 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 "Non-invasive ventilation vs oxygen therapy after extubation in patients with obesity in intensive care units: The multicentre randomised EXTUB-OBESE study protocol ".

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

Done in ...................................

Patient signature:



Done in ...................................

Physician signature:


