EXSUPEEP - 2022-A00334-39 - version n°2 of 02/10/2022

INFORMATION NOTE FOR THE RELATIVES OR TRUSTED PERSON

Positive end-expiratory pressure versus Extubation with endotracheal suction in intensive care patients. Prospective randomized multicenter study

EXSUPEEP" study

N°ID-RCB: 2022-A00334-39

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PART 1: RESEARCH INFORMATION

* Words or groups of words marked with an asterisk are included in the glossary.

Dear Sir/Madam,

Dr/Pr/Mrs/M ..... has introduced you to the ExSuPEEP study, research involving the human subject* which aims to evaluate two extubation techniques in intensive care patients, and is seeking your consent for your loved one to take part.

You are free to decide whether or not you want your loved one to take part. You can take as much time as you need to read the information below, talk to your loved ones and ask any questions you may have to the members of the medical team in charge, as well as to the doctor or physiotherapist involved in the research, known as the investigator*. Once your questions have been satisfactorily answered, and you have had sufficient time to think about it, you can then decide whether or not to allow your loved one to take part in the research.

Before making a decision, it is important that you read these pages carefully, as they will provide you with the necessary information on the various aspects of this research. Keep this document.

Signing the consent form, which has become compulsory under the French Public Health Code (Book I, Titles 2 and 3 of the CSP), in no way affects your loved one's legal rights.

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

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What does research involve?

Your loved one is currently hospitalized in intensive care with artificial ventilation, connected to the respirator with an intubation tube. We plan to remove the tube (extubation) as soon as possible, so that he/she can breathe naturally again. The decision to extubate is a **medical** one**.**

Extubation is not an emergency procedure, but is preceded by several stages. To ensure that you have enough time to read this information and ask any questions you may have, the investigator will inform you as far in advance of the procedure as possible.
However, the time frame depends on the individual case. Some situations cannot be anticipated beyond several hours.
Depending on your loved one's condition and medical situation, you will have between 2 and 72 hours - the time remaining before the extubation procedure - to consider whether your loved one should participate in this study.

Many studies have already helped us to know how to prepare patients properly and when is the right time.
We're currently looking at how to remove the intubation tube, and in particular whether or not to keep pressure on the lungs during the procedure.

This study will evaluate two methods used in current practice for extubation

Removing the intubation tube is one of the tasks of physiotherapists and intensive care nurses. This procedure is performed daily in intensive care units around the world. Yet it has rarely been studied.

The 2 most commonly used extubation practices are :

1) The probe is removed while **the ventilator is disconnected**, and secretions are **aspirated at the same time.**
2) Removal of the intubation tube is carried out while **the respirator is still connected,** under the application of **supportive pressure in the lungs**, an aspiration of secretions having taken place 3 minutes earlier.

Extubation is a quick, painless procedure. It may generate a need to cough, which is natural and encouraged in order to clear the patient's airways.
After extubation, your loved one may need occasional oxygen or ventilator support, via a mask, to rest his or her respiratory muscles.

The aim of our study is to determine whether the use of the second method when removing the intubation tube reduces the need for ventilator support in the 28 days following extubation.

How does the research work?

This study will evaluate the **two** commonly used **extubation methods**, helping to define the most beneficial technique for the patient and harmonize practices.

The extubation technique will be determined randomly using a mathematical methodology known as randomization, in line with international standard procedures. Half of the patients will benefit from extubation with concomitant suction (method 1) and the other half from extubation with supporting pressure (method 2)
Your loved one's participation in this study will in no way affect his or her day-to-day care, and nothing will be imposed by the study apart from the extubation method, which will be selected at random.
He/she will be monitored for 28 days as part of this research to assess his/her state of health

It is important that you discuss the matter with the investigator (or the healthcare professional representing the investigator) before deciding whether your loved one should participate.

What are the possible medical alternatives?

In the event of refusal to participate in the ExSuPEEP study, your loved one will benefit from standard care at the center where he/she is hospitalized, as well as from all diagnostic and therapeutic methods currently available.

What are the expected benefits and risks of research

Expected benefits

In clinical practice, catheter removal is usually performed in conjunction with bronchial aspiration.
If we assume that removal of the intubation tube at supportive pressure increases the number of days free of mechanical ventilation at D28, we can expect a reduction in care-related morbidity and mortality for the patient.

Potential risks

The risks and constraints associated with weaning methods are minimal.
Our entire extubation procedure complies with the most recent recommendations of learned societies. In addition, both methods of tube removal are widely used in routine practice throughout the world.

The only constraint is a telephone contact on the 28th day of inclusion if your loved one has been discharged from hospital.
No particular additional constraints are expected in terms of management strategy.

Compensation for hardship

Your loved one will not be compensated for his or her participation in this research.

He/she will not be able to participate in this trial if he/she is involved in another clinical trial that may affect the results of the research.

What happens if research is stopped prematurely, and what happens afterwards?

If you agree to your relative's participation in the study, but change your mind during the course of the study, or if your relative does not agree with your decision, you or he/she may, at any time, request that his/her participation in the study be discontinued without prejudice, without justification on his/her or your part, and without any liability on your or his/her part. The data collected up to that point will be used in the results of the study.

Data retention period

In accordance with French and European regulations, study data will be kept in an active database for up to 2 years after the last publication, then archived for 15 years from the study end date.

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Legislative and regulatory provisions

In accordance with article L. 1121-4 of the French Public Health Code, this research project received a favorable opinion from the Comité de Protection des Personnes Ile de France II on 04/11/2022.

The processing of personal data for research purposes complies with a reference methodology (MR) MR-001* established by the Commission Nationale Informatique et Libertés (CNIL).

To cover its liability and that of all persons involved in carrying out the research, in accordance with article L. 1121-10 of the CSP, the promoter of this research, the Centre Hospitalier Général Fleyriat - Bourg en Bresse, has taken out civil liability insurance with the Société Hospitalière d'Assurance Mutuelle, 18 rue Edouard Rochet, 69008 Lyon, under number 167924.

Once your loved one is capable of understanding and expressing his or her wishes, we will ask for his or her written consent to continue participating in the *ExSuPEEP* study.

PART 2: INFORMATION ON THE PARTICIPANT'S RIGHTS AND ON THE MANAGEMENT OF THE DATA COLLECTED

What does the principle of free and informed consent to participation in research involving the human person mean?

Participation in research involving the human body is free and voluntary: you are free to accept or refuse to participate, on behalf of your loved one, in this research study, and you may interrupt his or her participation at any time without having to give any reason and without incurring any liability or prejudice as a result. Simply inform the investigator.

Your decision whether or not to involve your loved one will have no impact on his or her medical management and quality of care, or on your or your loved one's relationship with the investigator.

To take part in research, you must first give your free and informed consent for your loved one's participation. "Informed" means that you have been given clear, comprehensible information on the issues and procedures of the research, and on your loved one's rights as a participant.

You will be informed by your investigator of any new information concerning the research that could affect your decision or his/her decision to participate (when he/she is capable of giving consent on his/her own).

You have the right to obtain communication, during or at the end of the research, of information concerning the health of your loved one, held by the investigator or, where applicable, the doctor or qualified person representing him or her.

How will your loved one's personal data* be processed in the context of research

If you agree to allow your loved one to take part in research, his/her personal data, including health data, will be processed* by the sponsor, in its capacity as data controller.

The following data will be collected:

- Age, month and year of birth, gender
- Autonomy before hospitalization
- Administrative data: date of admission to intensive care unit and length of stay in intensive care unit and hospital,
- All clinical and monitoring data: therapies undergone, medical history, daily vitals, clinical examinations, vital status, imaging studies, results of medical biology analyses, etc.

What is the legal basis and purpose of the processing of your relative's personal data?

The processing of your relative's personal data, as listed above, is necessary to carry out the research and is based on the public interest mission entrusted to the promoter.

This processing is authorized because it is necessary for scientific research purposes. The data controller must implement appropriate measures to guarantee your loved one's rights and freedoms, in particular by collecting only data that is strictly necessary for research purposes.

How will the confidentiality of your loved one's data be ensured?

Its personal data will be treated confidentially, in accordance with the amended law of January 6, 1978 known as the "Loi Informatique et Libertés", and in compliance with the General Data Protection Regulation (RGPD*).

His/her data will be coded*, i.e. he/she will be identified by a code number for the purposes of the research, without mentioning his/her first and last names. Only the investigator will keep the correspondence list between the code and his/her name.

Who will have access to your loved one's data for research purposes?

Information concerning your identity (surname, first name) will be known only by :

- the medical team caring for him/her
- persons carrying out research quality control mandated by the sponsor
- health or control authorities,
- the promoter's data protection delegate, if he/she contacts him/her at the following address: Center hospitalier Fleyriat, 900 route de Paris, 01012 BOURG-EN-BRESSE CEDEX or by email: dpo@ght01.fr
- in the event of a dispute, by the authorized personnel of the promoter's insurance company.

These people are bound by professional secrecy.

Its coded data will be accessible to the following people:

- The promoter and persons acting on its behalf (in particular Hospices Civils de Lyon)
- Independent experts responsible for re-analyzing data to verify research results, with a view to publication under strict safety conditions.

These people, who are bound by professional secrecy, will have access to coded data within the scope of their duties and in compliance with regulations.

What are your rights regarding your loved one's personal data?

He/she has the right to access his/her data, through the investigator, and to request that it be corrected or completed.

He/she may also request the restriction of the processing of his/her data (i.e. ask the promoter to temporarily freeze the use of his/her data).

Even if you agree to his/her participation in the research, he/she may at any time object to the processing of his/her data for the purposes of carrying out the research. In this case, no further information concerning him/her will be collected.

He/she may also exercise his/her right to erasure of data already collected, but such data may not be erased if this would make it impossible or would seriously compromise the achievement of the research objectives.

In addition, certain data intended to ensure the quality and safety of the research (e.g. adverse effects due to the experimental procedure) must be collected by the sponsor. He/she will not be able to exercise his/her right of opposition or deletion concerning these data.

He/she may also access all his/her medical data directly or through a doctor of his/her choice, in accordance with the provisions of article L. 1111-7 of the French Public Health Code.

To do so, a written request, specifying the date of hospitalization concerned, accompanied by a copy of your identity card, should be sent to the General Affairs Department of the Centre hospitalier Fleyriat, 900 route de Paris, 01012 BOURG-EN-BRESSE CEDEX.

How can your loved one exercise his or her rights?

He/she may exercise his/her rights at any time and without having to justify him/herself.

As the sponsor does not have access to your identity, we recommend that you first contact the investigator, whose contact details are given in this note.

He/she may also, if he/she so wishes, exercise his/her rights with the sponsor's data protection officer by e-mail:dpo@ght01.fr or by post: Centre hospitalier Fleyriat, 900 route de Paris, 01012 BOURG-EN-BRESSE CEDEX. He will manage this request in coordination with the physician and professionals involved in the study. In this case, the identity of your relative (first name, surname) will be made available to the sponsor's data protection officer.

Should he/she be unable to exercise his/her rights, he/she also has the right to lodge a complaint concerning the processing of his/her personal data with the Commission Nationale de l'Informatique et des Libertés (CNIL), which is the competent supervisory authority in France for data protection.

Can your loved one's coded data be reused?

He/she may accept or refuse the principle of using his/her coded data for further research, conducted exclusively for scientific purposes in the field of resuscitation

If he/she accepts the principle, he/she will be contacted again to be informed of the characteristics of the new protocol(s) in accordance with Article 14 of the RGPD, and if he/she does not object his/her coded data may be reused and transmitted for these other health research projects.

This/these subsequent research(s) must either comply with a reference established by the CNIL if it/they fall(s) within the scope of a simplified procedure due to its/their characteristics, or be subject to authorization by the CNIL.

Thanks to this information, he/she can choose to exercise his/her rights of access, rectification, limitation, opposition or deletion of his/her data.

Opposition procedures for each research project will be indicated on the information note sent to the applicant.

The entire team would like to thank you and will be happy to answer any questions you may have.

GLOSSARY

Search Involving the human person	Research organized and carried out on human beings with a view to developing biological or medical knowledge is referred to as "research involving the human person" (article L. 1121-1 of the French Public Health Code).
Developer	The natural or legal person responsible for the research, who manages it and ensures that it is properly funded.
Investigator	An individual responsible for supervising and directing research at a research site.
RGPD	General Data Protection Regulation. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
Randomized study	A study in which group assignment is randomized by drawing lots.
Overall results	Research results resulting from the analysis of all research data.
Personal data	Data relating to an identified or identifiable natural person. Health data is particularly sensitive personal data.
Coded data **Or pseudonymized**	Encoding or pseudonymization consists in replacing directly identifying data (surname, first name, etc.) in a data set with indirectly identifying data (alias, number, etc.).
Reference Methodology (RM)	Simplified health data access procedure for research sponsors
Data processing	Personal data processing is any operation, or set of operations, relating to personal data, regardless of the process used (collection, recording, organization, conservation, adaptation, modification, extraction, consultation, use, communication by transmission or dissemination or any other form of provision, reconciliation).

CONSENT FORM FOR RELATIVES or to THE TRUSTED PERSON

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V2.0 dated 02/10/2022

I, the undersigned [Last name, First name] .....,
acting in the capacity of relative or trusted person of [*Last name, First name*] ....., freely consent to authorize the participation of my relative in this research as described in the information letter and I confirm the following points:

- I've had time to read the information, think about the study and get appropriate answers to my questions.
- I have been fully informed of the nature of the research objectives, the potential risks and the constraints associated with this research.
- I certify that my family member is affiliated to a social security scheme or is a beneficiary of such a scheme.
- He/she will have the right to refuse to participate in the research or to withdraw his/her consent at any time without any consequences for his/her medical care and without incurring any liability or prejudice as a result.
- I understand that my loved one may interrupt his/her participation in this research at any time without having to justify his/her decision. He/she must inform the investigator who is following him/her in the research. This will not affect the quality of his/her subsequent care.
- I understand that the investigator may interrupt his or her participation in the research at any time if he or she deems it necessary.
- I have noted that he/she has the right to access, rectify, limit and, if necessary, object to and delete the processing of his/her personal data. These rights may be exercised in the first instance with the investigator who is following him/her as part of this research and who is aware of his/her identity.
- I have been informed that this research has been approved by the Comité de Protection des Personnes Ile de France II. The research sponsor has taken out civil liability insurance in the event of injury with Société Hospitalière d'Assurance Mutuelle, 18 rue Edouard Rochet, 69008 Lyon.
- My consent in no way relieves the investigator and the research sponsor of their responsibilities towards my relative. He/she retains all rights guaranteed by law.
- The overall results of the research will be communicated to him/her at the end of the research, if he/she so requests from the investigator.
- He/she will not be able to participate in any other research with the same endpoints during his/her participation in the present study.
- After the research has begun, he/she may at any time request further information from the healthcare professional collecting my consent on his/her behalf.
- Two original copies of this consent form have been drawn up: one has been given to me, the second has been kept by the investigator. It will be kept in the study file for at least 15 years after the end of the research.
- I have been informed about how my relative's personal data may be collected, used and shared as described in this document.

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If necessary for the continuity of his or her care, I agree that his or her attending physician may be informed of his or her participation	Yes □ No □

Signatory in case of impossibility by the participant him/herself "When it is impossible for the person concerned to express his/her consent in writing, it may be attested by the trusted support person provided for in article L. 1111-6, by a family member or, failing this, by one of the close relatives of the person concerned, provided that this trusted support person, family member or close relative is independent of the investigator and the sponsor" (Article L. 1122-1-1 of the French Public Health Code).
Surname and first name of relative or trusted person : ....
Relationship with the patient :
Date of signature |___|___| / |___|___| / |___|___|___||
Signature of relative or support person :
Surname and first name of investigator or doctor who informed next of kin/trusted person ....
Date of signature |___|___| / |___|___| / |___|___|___||
Signature of investigator or physician who informed next of person

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