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PATIENT INFORMATION NOTE FURTHER RESEARCH

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,

You are or have been hospitalized in an intensive care unit. During your stay, you required intubation. As part of your extubation, a family member or a trusted support person has been asked ask you to take part in a research project involving the human body*, the aim of which is to evaluate two extubation techniques in intensive care patients. Your relative or support person has agreed to your participation in the study

Today, Dr/Pr/Mrs/M ..... proposes that you continue your participation in this study.

You are free to decide whether or not to continue your participation. You can take as much time as you need to read the information below, discuss it with your family and your GP, and ask any questions you may have 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 reflect, you can then decide whether or not to continue your participation 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 continuation form, which has become compulsory under the French Public Health Code (Livre I, titres 2 et 3 du CSP), in no way affects your legal rights.

[illegible]y voluntary. If you do not wish to continue your participation in this research, you will [illegible] best possible medical care, in accordance with current knowledge.

Sedillot N, *et al. BMJ Open* 2025; 15:e092354. doi: 10.1136/bmjopen-2024-092354

What does research involve?

You have been admitted to the intensive care unit on artificial ventilation, connected to the ventilator with an intubation tube. We plan to remove the tube (extubation) as soon as possible, so that you can breathe naturally again. The decision to extubate is a **medical** one**.**
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 **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 the need to cough, which is natural and encouraged in order to clear your airways.
After extubation, you may need occasional oxygen or ventilator support, via the use of a mask, to rest your 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 you received was randomly determined using a mathematical methodology known as randomization, in accordance with international standard procedures. Half of the patients benefited from extubation with concomitant suction (method 1) and the other half from extubation with supporting pressure (method 2)

Your participation in this study in no way altered your day-to-day care. Nothing was imposed on you by the study, apart from the method of extubation, which was chosen at random.
You will be monitored for a maximum of 28 days to assess your state of health.

To participate in this study, you must adhere to the study schedule. It is important that you discuss your participation with the investigator (or the healthcare professional representing him or her) before deciding whether to continue.

What are the possible medical alternatives?

In the event of withdrawal from the ExSUPEEP study, you will continue to benefit from the standard care of the center in which you are hospitalized, as well as from all diagnostic and therapeutic methods currently available.

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efits and risks of research

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 day 28th of inclusion if you have been discharged from hospital.
No particular additional constraints are expected in terms of management strategy.

Compensation for hardship

You will not be compensated for your participation in this research.

You will not be able to participate in this trial if you are taking part in another clinical trial that could affect the results of the research.

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

If you decide to continue your participation in this research, but change your mind during the course of the study, you may request to discontinue your participation at any time without any prejudice, justification or liability on your part. Your personal 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 end of the study.

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 your personal data in the context of research 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.

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?

Your participation in a research study involving the human body is free and voluntary: you are free to accept or refuse to continue your participation in this research study, and you may interrupt it 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 continue your participation will have no impact on your medical management, the quality of your care or your relationship with the investigator.

To take part in research, you must first give your free and informed consent. "Informed" means that you have been given clear, comprehensible information on the issues at stake and how the research will be carried out, and on your rights as a participant.

You will be informed by your investigator of any new information about the research that could affect your decision to participate.

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

If you so wish, you may be informed of the overall results of this research, in accordance with the provisions of article L. 1122-1 of the French Public Health Code, once it has been completed, through the intermediary of the investigating physiotherapist or the referring physician for the study who has followed you as part of this research.

How will your personal data* be processed for research purposes?

If you agree to take part in research, your personal data, including your 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: your date of admission to intensive care and your length of stay in intensive care and in hospital,
- All clinical and monitoring data: therapies undergone, medical history, daily vitals, clinical examinations, vital status, imaging studies, results of medical biology analyses.

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

The processing of your personal data 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 rights and freedoms, in particular by collecting only data that is strictly necessary for research purposes.

How is the confidentiality of your data ensured?

Your personal data is treated confidentially, in accordance with the French Data Protection Act of January 6, 1978, as amended, and in compliance with the General Data Protection Regulation (RGPD*).

Your data is coded*, i.e. you are identified by a code number for research purposes, without mentioning your first and last names. Only the investigator keeps the correspondence list between the code and your name.

Who has access to your data for research purposes?

Information concerning your identity (surname, first name) is known only to :

- the medical team taking care of you
- persons carrying out research quality control mandated by the sponsor
- health or control authorities,
- the promoter's data protection delegate, if you contact him 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.

Your coded data can be accessed by 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, have access to your coded data within the scope of their duties and in compliance with regulations.

What are your rights regarding your personal data?

You have the right to access your data, via the investigator, and request that it be corrected or completed.

You may also request the restriction of the processing of your data (i.e. ask the promoter to temporarily freeze the use of your data).

Even if you agree to continue your participation in the research, you may at any time object to the processing of your data for the purposes of carrying out the research. In this case, no further information about you will be collected.

You may also exercise your right to erasure of data already collected, but this 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. undesirable effects due to the experimental procedure) must be collected by the sponsor. You will not be able to exercise your right to object to or delete this data.

You may also access all your medical data directly or through a doctor of your choice, in accordance with 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, must be sent to the General Affairs Department of the Centre hospitalier Fleyriat, 900 route de Paris, 01012 BOURG-EN-BRESSE CEDEX.

How to exercise your rights

You can exercise your rights at any time and without having to justify yourself.

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.

You may also, if you wish, exercise your 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, your identity (first name, surname) will be made available to the sponsor's data protection officer.

In the event that you are unable to exercise your rights, you also have the right to lodge a complaint concerning the processing of your 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 coded data be reused?

You can accept or refuse the principle of using your coded data for further research, conducted exclusively for scientific purposes in the field of resuscitation

If you agree in principle, you 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 you do not object your 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, you can choose to exercise your rights of access, rectification, limitation, opposition or deletion of your data.

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

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, involving personal data, regardless of the process used (collection, recording, organization, storage, adaptation, modification, retrieval, consultation, use, communication by transmission or dissemination or any other form of making available, matching).

WRITTEN CONSENT FORM FOR

FOR FURTHER RESEARCH

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

EXSUPEEP" study

ExSuPEEP study

V2.0 of 07/19/2022

I, the undersigned [Last name, First name] ..... freely consent to continue my participation in this research as described in the information letter and 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 I am a member of a social security scheme or a beneficiary of such a scheme.
- I have the right to refuse to participate in the research or to withdraw my consent at any time without any consequences for my medical care and without incurring any liability or prejudice as a result.
- I have fully understood that I can interrupt my participation in this research at any time without having to justify my decision, and I will inform the investigator who is following me in the research. This will not compromise the quality of subsequent care.
- I understand that the investigator may interrupt my participation in the research at any time if he deems it necessary.
- I have noted that I have the right to access, rectify, limit and, if necessary, object to and delete the processing of my personal data. These rights may be exercised in the first instance with the investigator who is following me as part of this research and who is aware of my 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 me. I retain all my rights under the law.
- The overall results of the research will be communicated to me at the end of the research, if I request it from the investigator.
- I will not be able to participate in any other research during my participation in this study.
- In the event of an examination likely to detect abnormalities, I agree to be kept informed of information concerning my state of health and any abnormalities that may be detected during the research.
- I may at any time request additional information from the healthcare professional who obtained my consent for this research.
- Two original copies of this consent form have been drawn up: one has been given to me, the second kept by the investigator. They 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 personal data may be collected, used and shared as described in

this document.

If necessary for the continuity of my care, I accept that my attending physician be informed of my participation in this research.	Yes □ No □
I agree that my coded personal data may be used for other research related to intensive care, exclusively for scientific purposes, with the understanding that I may withdraw my consent at any time.	Yes □ No □

Last name and first name of participant .....
Date of signature |___|___| / |___|___| / |___|___|___||
Signature of participant
Last name and first name of investigator or physician who informed participant .....
Date of signature |___|___| / |___|___| / |___|___|___||
Signature of investigator or physician who informed participant