ANNEX 4. INFORMATION TO PATIENTS

Ethics Committee Approval Number:

STUDY INFORMATION SHEET FOR PATIENTS AND CONSENT FORM

STUDY INFORMATION SHEET FOR PATIENTS

(VERSION 1.0, February 2019)
Number of approval by the Ethics Committee:

Name of the study: FRAilty incidence in surGIcal European patients **(FRAGILE).**

European prospective cohort study of the prevalence of frailty in surgical patients.

Dear patient,
You have been invited to participate in a research study. We would like to explain to you why this study is being conducted and what it will entail for you. Please take the time to carefully read the following information and discuss it with other people, if you wish. Please ask us if something is unclear or if you need more information. Take your time to decide if you want to participate. Your participation is important to obtain the knowledge we need, but before making a decision you must:
- Read this entire document
- Understand the information contained in the document
- Ask all the questions you consider necessary
- Consult with your doctor-trusted person
- Make a thoughtful decision
- Sign the informed consent, if you finally want to participate.

If you decide to participate, you will be given a copy of this document and signed consent. Please keep them in case you need it in the future.

Why are you asked to participate?
You have been invited to participate in this study, because you must undergo surgery. The FRAGILE is an international observational study, with the participation of centres worldwide. This means that routine clinical practice will not change, and no additional or alternative treatment will be performed. Instead, data of routine clinical practice will be collected.

What is the purpose of this study?
Our main objective is to carry out an observational study to determine the prevalence of frailty in the surgical patient, and its possible relation with postoperative outcomes like quality

of life and hospital length of stay. We also aim to assess which measures that could potentially improve the prognosis of frail patients are being adopted at the present time, and the relation between these measures and patient clinical outcomes. Several studies show a direct association between frailty and a slowing-down in patient recovery, a non-recovery of the preoperative status and even a higher risk of mortality than non-frail patients.

What do I have to do if I decide to participate?

Remember that your participation is voluntary and if you decide not to participate this will not affect your attendance or your relationship with the researcher. If you decide to participate, the researchers will collect preoperative data derived from the pre-anesthesia consultation, as well as data on the surgical intervention and postoperative data. Always so that these data remain anonymous. Given that this is an observational study, no additional intervention will be made to those that are performed regularly in your center. Neither will any extraordinary test be performed, and of course, planned tests will not be dispensed with.

It is not required that you make more visits to the hospital, either before or after the surgery. Sólo le llamaremos por teléfono a los 30 días de la intervención quirúrgica para evaluar su estado de salud.

Do I have an obligation to participate?

No, your participation is completely voluntary. If you decide to participate, please sign the consent form to show that you agree to participate and keep the copy that is delivered with this information sheet. If you decide not to participate in the study, your decision will not affect your treatment or the care you are receiving at this time or that you will receive in the future.

Will I get any benefit for participating?

Being a research study aimed at generating knowledge, it is not expected that you will obtain direct benefit by participating or will receive any financial compensation for it, although you will contribute to the advancement of knowledge and social benefit.

What risks or inconveniences does it have to participate?

FRAGILE is an observational study, therefore your treatment will not change because you participate in this study. Perioperative treatment (before, during and after your surgery) will be prescribed according to the healthcare practice and your needs as a patient and will not be altered by the inclusion in the study.

Risk for confidentiality

The clinical information obtained in this project will be stored in a database protected by current legislation, under the responsibility of the responsible institutions' investigators. These anonymized data will be kept for future studies, unless you indicate otherwise. The results of this research can be disseminated in journals, medical databases and scientific forums. Personal data that could identify you will never be revealed. The investigators will always have a duty to protect your privacy and maintain all your information confidentially.

Privacy and use of clinical information

The treatment, communication and transfer of your data will be performed according the Regulation (EU) 2016/679 of the European Parliament and the April 27th 2016 Council on Data protection (RGPD). The principal investigators, Dr Carlos Ferrando and Dr César Aldecoa, will be accountable for the custody of the participants' identification codes. As a participant, you may exercise your rights of access, rectification, objection and/or deletion, by contacting any of the principal investigators (telephone numbers provided at the end of this document). Moreover, you can restrict processing of incorrect data, request a copy of your data or request
the transfer of your data to a third party (portability). You may exercise your rights by contacting the principal investigators of the study [Carlos Ferrando (cafeoranestesia@gmail.com), César Aldecoa (cesar.aldecoa@gmail.com)]. We remind you that data cannot be delated even though you cease to take part in the study, in order to guarantee the study's validity and to comply with the legal and medicinal products requirements for authorisation. You are entitled to contact the Data Protection Agency if not satisfied. Both the Centre and the Promoter are responsible for data treatment and they commit to meet the data protection regulations in force. Data collected for the study will be identified with a code, so that no information that could identify you is not included. Only your doctor and collaborators will be able to relate your data with you and your clinical history. Therefore, your identity will not be revealed to anyone, except for the healthcare authorities whenever required or in cases of medical emergency. Ethical Committees, healthcare authorities' representatives and authorised personnel will only have access to data in order to perform checks on personal data, on the study procedures and on the compliance with the Good Clinical Practice Standards (always maintaining confidentiality).
The principal investigator and the promoter are obliged to keep all the data collected throughout the study for at least 25 years after the end of the study. After that, your personal data will only be stored at your hospital for your health care. In case we transfer your encoded data outside the EU, to scientific researchers or service providers that collaborate with us, your data will be safeguarded by contracts or other mechanisms recommended by data protection authorities. Further information can be obtained by contacting the Data Protection Delegate (Carlos Ferrando Ortolá, cafeoranestesia@gmail.com).

Withdrawal from the study

Even though you have agreed to participate, you may leave the study whenever you wish without any effect on your medical care and without having to offer any explanation. All you need to do is express your intention to the study's principal investigator or his collaborators. If you decide to withdraw from the study, no further data will be collected, while already collected data will be filed.

How can I know the results of the study?

You have the right to know the results of this study, both the general results and those derived from your specific data. You also have the right not to know these results if you wish. For this reason, in the informed consent document, we will ask you which option you prefer. In case you want to know the results, the researcher will send you the results. The overall results of this study will be sent to medical and scientific publications and presented at meetings in the same field for dissemination. The FRAGILE (NCT04140370) website (www.grupogerm.es/fragile) will also provide study data and updated recruitment information, both for patients and for the general public.

¿What if I have any questions during my participation in the?
In case you have any question or doubt regarding your participation, you can contact the principal investigators at Hospital Clínic de Barcelona (Carlos Ferrando, Chief of the surgical ICU) o at Hospital Río Hortega de Valladolid (César Aldecoa, Chief of the Anesthesiology department), during working hours (08:000-15:00) or by email to the aforementioned addresses.

Who is organizing and funding this research?
This study is being carried out by a network of doctors from all over the world. The study is coordinated by Dr. Carlos Ferrando and Dr César Aldecoa. The study is funded by the Spanish Group of Multimodal Rehabilitation (GERM).

Are there economic interests in this study?
Researchers will not receive specific retribution for the dedication to the study (in addition to their usual salary as researchers or doctors). You will not be rewarded for participating. There is no possibility of this study generating benefits in the form of patents.

Who has reviewed this study?
This research study has been reviewed by an independent group of people from a Research Ethics Committee, to protect your safety, your rights, your well-being and your dignity. The Healthcare Ethics Committee of the Hospital Clínic y Provincial de Barcelona has reviewed the study and has given the approval to carry it out.

What am I supposed to do now?
You must decide if you want to participate in this study. Please, think about what participating in the study involves and talk with your friends and family. The research doctor and the nurse will be happy to answer any questions you may have. When you decide, please inform your doctor. You will be asked to sign a consent form and you will be given a copy that you must keep attached to this information sheet. Please keep these documents. If at any time you have any questions about the study, you can contact the researchers of the FRAGILE study, whose contact information is indicated at the end.

Who can give me more information?
For further information, do not hesitate to contact:
Carlos Ferrando
Telephone number: 609892732
E-mail address: cafeoranestesia@gmail.com

César Aldecoa
Telephone number: 657500031
E-mail address: cesar.aldecoa@gmail.com

Study Title:

FRAilty incidence in surGIcal European patients (FRAGILE)

European propective cohort of the prevalence of frailty in surgical patients.

I, ... (name and surname of the participant) with ID card……, confirm that:
I have read and understood the information sheet that has been provided.
I have had the opportunity to ask questions and I have received satisfactory answers.

I have talked to :.....(name of the researcher)
I understand that my participation is voluntary.
I understand that I am free to withdraw from the study:
1) at any time
2) without giving any reason
3) without my medical care being affected.

I hearby agree to take part in the study.
Do I want to be informed about the results of the study: yes no (check what applies).
I agree that my medical data may be looked at by individuals from the FRAGILE Team and I am aware that this consent may be withdrawn at any time. Doy mi conformidad para que el equipo investigador me pueda llamar por teléfono a los 30 días de la cirugía
I have recieved a signed copy of this Consent Form.

Signature of the patient:

Date:

I have explained the study and its purpose to the patient.
Signature of the researcher:

Date:

ORAL WITNESSED CONSENT FORM

The declaration of the impartial witness is compulsory when the patient, the father or mother of the patient or the legal representative are incapable of reading or writing.

Study Title:

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European prospective cohort of the prevalence of frailty in surgical patients.

I, ... (name and surname of the participant) with ID card……, confirm that:
I have received the information sheet.
I have had the opportunity to ask questions and I have received satisfactory answers.
I have been provided with adequate information about the study.

I have talked to :.....(name of the researcher)
I hereby declare, under my own responsibility, that: …… (name of the participant) with ID card ……:
Understands that his/her participation is voluntary.
Understands that he/she is free to withdraw from the study:
1) at any time
2) without giving any reason
3) without my medical care being affected.
Has freely expressed his/her agreement to participate in the study.

Signature of the witness Signature of the researcher

Date Date

LEGAL REPRESENTATIVE CONSENT FORM

Study Title:

FRAilty incidence in surGIcal European patients (FRAGILE)

European prospective cohort of the prevalence of frailty in surgical patients.

I, ... (name and surname of the legal representative) with ID card…… and as …….. confirm that:
I have read and understood the information sheet that has been provided .
I have had the opportunity to ask questions and I have received satisfactory answers.
I have been provided with adequate information about the study.

I have talked to :..... (name of the researcher)
I understand that the participation in the study is voluntary.
I understand that it is possible to withdraw from the study:
1) whenever the participant may want to.
2) without giving any reason
3) without the medical care being affected.

In my presence, it has been given to …….. (name of the participant) all the necessary information adapted to his/her level of understanding and agrees to participate in the study. I hereby agree to …… (name of the participant) participating in the study.

Signature of the legal representative Signature of the researcher

Date Date