Official Title of the study:

"Study of an Intraoperative Frontal Electroencephalographic Marker of Preoperative Frailty in Patients Over 65 Years of Age for Elective Non-cardiac Surgery."

NCT number: NCT04783662

Date of the document: January 14th, 2021

INFORMED CONSENT DOCUMENT

Study Name: "Study of an intraoperative frontal electroencephalographic marker of preoperative fragility in patients older than 65 years in elective non-cardiac surgery."
Study Sponsor / Funding Source: Society of Anesthesiology of Chile and Faculty of Medicine Pontificia Universidad Católica de Chile.
Responsible Researcher: Dr. Juan Cristóbal Pedemonte Trewhela
Contact phone: 223543414 - 223543270
Dept./UDA: Anesthesiology

The purpose of this information is to help you make the decision to participate in medical research.

Take the time you need to make up your mind, read this document carefully, and ask your doctor or study staff any questions you want.

RESEARCH OBJECTIVES

Frailty increases postoperative complications in people over 65 years of age. This is defined as a state of vulnerability in which the patient finds it difficult to return to his or her baseline state of health after a stressful event, such as surgery. Currently there are different scales for its measurement. All of them require adequate execution time, an experienced evaluator and a prior validation process. The best scale to measure frailty in the perioperative period is unknown.

During surgery, EEG (electroencephalography) monitoring can be used using a forehead electrode band. It has been described that certain elements of the EEG change with age, physical and cognitive capacity in older patients.

You have been invited to participate in this study because you are over 65 years of age and are going to have elective surgery under general anesthesia.

The purpose of this study is to determine if some elements of the intraoperative EEG (alpha spectral power and the entire spectral band power) are associated with preoperative frailty in adults over 65 years estimated with various scales (FRAIL, Fried and CFS) during the preoperative anesthesia evaluation.

We hope to recruit a total of 60 patients in this investigation.

INVESTIGATION PROCEDURES

If you agree to participate in the study, you will be asked the following:

Before surgery:
1. To answer a cognitive test (ability to perceive, comprehend and understand) called MiniCog that takes about 5 minutes. In case this test is altered, a more detailed cognitive test called MOCA will be performed, which takes 5 to 10 minutes.
2. Your degree of frailty (functional reserve, weakness) will be assessed using 3 different instruments called: Clinical Frailty Scale (CFS) lasting 1-minute, FRAIL scale lasting 5-minutes and FRIED Phenotype lasting 5-minutes.

In the operation room:
1. Your vital signs will be monitored as is routine for this type of surgery.
2. A SedLine® forehead EEG headband will be fitted and requested upon closing your eyes to obtain a baseline recording for 5 minutes.
3. Intraoperatively, while you sleep, your brain waves will be recorded.

In the post anesthesia care unit:
1. Postoperative delirium evaluation will be performed using the CAM / CAM-ICU tool one hour after admission to the recovery room, which takes about 15 minutes.

We will also obtain information from your clinical records. The data obtained will be only used for the purpose of this investigation. If in the future they are used for other purposes than those of this medical research, a new consent will be requested.
Genetic studies will not be performed in this study.
The results obtained will be informed to you, as well as to your treating physician, who will indicate the most appropriate course of medical action for you; and you will be informed of the most appropriate medical course of action for your condition.

BENEFITS

You will not directly benefit from participating in this medical research. However, the information that will be obtained will be useful to learn more about whether the electroencephalogram in older people under general anesthesia is associated with preoperative frailty.

RISKS

Your participation in this study may cause you some kind of discomfort when answering the questions of the questionnaires covered in the interview.

COSTS

Your participation in this study will not mean any additional cost to the one already associated with the procedure for which you are being treated at this center.

Your participation in this study will cover the expenses associated with the evaluation of frailty and intraoperative monitoring with electroencephalography. However, the study will not cover those expenses associated with your health condition such as (controls inherent to your health condition, surgery requested by your treating physician, medications associated with your pathology, etc.).

DAMAGE COVERAGE

If there is any damage directly associated with the protocol, the event will be financed by the Division of Anesthesiology of the Faculty of Medicine Pontificia Universidad Católica de Chile.

COMPENSATIONS

This study does not contemplate any type of compensation for participation in it.

CONFIDENTIALITY OF INFORMATION

The information obtained will be kept confidential. Your name, RUT, test results or any identifiable information will be encoded in a database, using computer code. This information will be stored for 4 years under the responsibility of the Principal Investigator Dr. Juan Cristóbal Pedemonte.

It is possible that the results obtained will be presented in medical journals and conferences, however, your name will not be known.

WILLFULNESS

Your participation in this research is completely voluntary. You have the right not to agree to participate or to withdraw your consent and withdraw from this research at the time you consider convenient. By doing so, you do not lose any rights to assist you as a patient at this institution and the quality of medical care you deserve will not be affected.
If you withdraw your consent, for security reasons it may be necessary for us to analyze your data obtained up to that point. We will do this ensuring your confidentiality.

QUESTIONS

If you have questions about this medical research, you can contact or call Dr. Juan Cristóbal Pedemonte, Investigator Responsible for the study, at phone: 23543270 and email: jcpedemo@gmail.com

If you have questions about your rights as a participant in medical research, you can call Dr. Claudia Uribe Torres, President of the Scientific Ethics Committee in Health Sciences of the Pontificia Universidad Católica de Chile, at 223542397-223548173, or send an email to: eticadeinvestigacion@uc.cl

CONSENT STATEMENT

● The purpose of this medical research, the procedures, risks, benefits and rights that assist me have been explained to me and that I can withdraw from it at any time I wish.
● I sign this document voluntarily, without being forced to do so.
● I am not waiving any rights to assist me. I will be informed of any new information related to the study that arises during the study and that may be of direct relevance to my health condition
● I have been informed that I have the right to reassess my participation in this medical research at my discretion and at any time I wish.
● I authorize the responsible researcher and her collaborators to access and use the data contained in my clinical record for the purposes of this medical research.
● Upon signing, I am given a signed copy of this document.

MANDATORY SIGNATURES:

Competitor:

Name: ……..

Signature Date……

Responsible Researcher or Delegate:

Name: ……..

Signature Date……

Director of the Institution or his Delegate:

Name: ……………………………………………………………………………………………..

Signature Date……………………………………………