Study: "Association Between Burst Suppression During Anesthetic Induction With Postoperative Delirium in Cardiac Surgery"

NCT number: pending

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INFORMED CONSENT DOCUMENT

Study Name: Study of burst suppression during anesthetic induction with propofol in cardiac surgery in patients older than 65 years and its association with postoperative delirium.

Study Sponsor / Funding Source: Pharmacology and Toxicology Program, Faculty of Medicine, Pontificia Universidad Católica de Chile.

Responsible Researcher: Juan Cristóbal Pedemonte Trewhela Contact phone: 223543414 - 223543270

Department / 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

Neurocognitive disorders during the perioperative period, such as postoperative delirium, are the leading cause of preventable disease in people over 65 years of age. Post-operative delirium is an acute brain dysfunction characterized by changes in attention and cognition that can occur within the first week after surgery.

To prevent postoperative delirium, different strategies are used, among them is the monitoring of the electroencephalogram (EEG) using a headband on the forehead. During surgery, the EEG is used to look for a signal called burst suppression. This is a characteristic pattern that is frequently observed in older people under general anesthesia. You have been invited to participate in this study because you are over 65 years old and you are going to undergo elective surgery for heart surgery that requires extracorporeal circulation: coronary bypass or valve replacement.

The purpose of this study is to determine whether burst suppression in the elderly during the initiation of propofol anesthesia is associated with postoperative delirium in comparison with the elderly who do not have burst suppression.

INVESTIGATION PROCEDURES

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

Before surgery, during the pre-anesthetic evaluation:
1. Answer a cognitive test (ability to perceive, comprehend and understand) called MiniCog that takes about 5 minutes.
2. Your degree of frailty (functional reserve, weakness) will be evaluated using an instrument called the Clinical Frailty Scale, which takes about 1 minute.
3. You will be tested for delirium symptoms with a specialized form called the Confusion Assessment Method that takes about 15 minutes.

In the operation room:
1. Your vital signs will be monitored as is routine for this type of surgery.
2. Once you are calm, a baseline blood sample will be taken for evaluation of inflammatory markers of about 5 ml (one teaspoon). Obtaining the sample will be done through one of the i.v. routes that will be placed for your surgery.
3. A frontal EEG headband will be fitted and you will be asked to close your eyes to obtain a baseline recording for 5 minutes.

In recovery room:
1. Post-operative delirium assessment will be performed using the Confusion Assessment Method twice a day, the first 72 postoperative hours, where you will be asked to answer some questions that take about 15 minutes.

The sample obtained will be used solely for the purpose of this investigation. If in the future they are used for purposes other than those of this medical research, a new consent will be requested.
Genetic studies will not be done in this study.

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 suppression of the electroencephalogram in the elderly during the initiation of propofol anesthesia is associated with postoperative delirium.

RISKS

The risks to you from participating in this study are low. Your cooperation may cause you some kind of discomfort when completing the questionnaires or when taking a blood sample.

COSTS

Your participation in this study will not mean any additional cost to that already associated with the procedure / condition for which you are being treated at this center. Your participation in this study will cover the costs associated with taking a blood sample and testing for the inflammatory marker. 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

In the event of 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, ID, 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, his 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 deem appropriate. By doing so, you do not lose any rights to assist you as a patient of this institution and the quality of medical care you deserve will not be affected.

If you withdraw your consent, your samples will be deleted and the information obtained will not be used.
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

STATEMENT OF CONSENT

● 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 medical device that arises during the study and that may be of direct importance 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 .....