Impact of Propofol Dose Reduction in Relation to the Time Since Administration of Fentanyl During Anesthesia Induction

NCT number: 04194151

October 24th, 2017

PATIENT INFORMATION AND INFORMED CONSENT

Dear Patient:

The purpose of this document is to inform you of the possibility to participate in a totally voluntary way in a research project that we are carrying out. We will explain the various aspects of the project, so you can decide if you want to participate.

This is a research study on the time and doses administered for anesthetic induction, the time at which the optimal anesthetic depth is reached and the hemodynamic changes that this generates, which is completely foreign to any aspect related to the pathology for which you are being intervened. The participation in this trial, whose title is "Assessment of the reduction in the dose of propofol in relation to the time since the administration of fentanyl during anesthetic induction", is COMPLETE voluntary.

The objective of this study is to assess whether it is possible to reduce the dose of propofol necessary for anesthetic induction when the time since administration of fentanyl is prolonged.

As you have been informed previously by the anesthesiologist, you need the administration of general anesthesia for the surgery you are scheduled. For this, it is required to monitor your heart rate and blood pressure in a non-INVASIVE manner, among other parameters, to assess your hemodynamic state while you are asleep.

The study consists of registering your data (age, sex, weight, antihypertensive medication -if you take any-, classification of anesthetic risk according to the American Society of Anesthesiology, heart rate, blood pressure and Bispectral Index value) before being asleep. The Bispectral Index monitor is a monitor that measures your brain activity using a sensor that sticks to the forehead to determine the degree of anesthetic depth.

According to usual practice, venous access is achieved and anesthetic drugs will be administered at a timed interval and at clinical doses, recording your heart rate, blood pressure and the time it takes to reach the optimal anesthetic depth.

Participation in this study is ABSOLUTELY VOLUNTARY and you may decide to withdraw permission to use your data at any time.

Benefits and Risks

You will not get any personal benefit from participating in this study, but the knowledge gained from this research can help improve the care of future patients.

Because the drugs that will be provided to you are those that are routinely administered, no condition that could cause harm, pain or suffering will be altered, nor will your level of sedation be compromised. The risks of general anesthesia that have been previously explained in the Anesthesiology and Resuscitation office are not altered by this data record.

Refusal to participate does not affect the care or relationship with your doctors.

Confidentiality

The information recorded in this study will be protected to maintain confidentiality according to current data protection laws. We will not provide any information that identifies you, your personal data will not be published in the scientific press without your authorization and will only be identified with investigation fines.

According to the Organic Law of Protection of Personal Data (15/1999 of December 13), all personnel related to the study are obliged to protect the confidentiality of the data of the participants; and at any time you can exercise your rights of access, rectification, cancellation and opposition, send a written request accompanied by a photocopy of the official identity document to the Anaesthesiology and Resuscitation Service of the Hospital Central de la Defensa "Gómez Ulla", Glorieta del ejército s/n, 28047, Madrid (Madrid).

The anesthesiologist Dr. Paula Agostina Vullo is at your disposal to answer any questions you may have, being your phone number +34 *** *** 151.

In consecuense,

I, D./Dña. ... ……, of… .. years of age and with ID number …… stated that he previously demonstrated the information described. Dr. Vullo has clearly informed me of the implications of my participation in this study.

I understand that my participation is voluntary and that I can withdraw from the study whenever I want, without having to give explanations and without this having an impact on my medical care.

Madrid, …… 20 ……

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Doctor Patient / Legal tutor