PATIENT INFORMATION SHEET AND INFORMED CONSENT

Title of the study: "**Individualized PeriopeRative Open lung Ventilatory stratEgy in patients submitted to One Lung Ventilation (iPROVE-OLV): study protocol for an international multicenter randomized controlled trial.**"

NTC:
Sponsor: Dr. F. Javier Belda
Principal Investigator of the study: Carlos Ferrando and Carmen Unzueta
Center: <Insert center name>
Principal Investigator of the center:
which is being carried out by Dr. Carlos Ferrando of the Anaesthesiology and Critical Care Department and which has already been evaluated and approved by the Clinical Research Ethics Committee of the University Clinical Hospital of Valencia.

Dear Patient:
You have been invited to participate in a research study. This consent document contains information that will help you decide if you want to participate. Take your time, read this consent document carefully and ask the doctor or study staff any questions you want. Do not sign this document until you understand all the information presented in the following pages and all your questions about the study have been answered satisfactorily. The study has been evaluated and approved by the Clinical Research Ethics Committee of the Hospital Clínico Universitario de Valencia.

Background:
It is now known from various studies that mechanical ventilation, usually used in patients undergoing general anesthesia to perform a surgical intervention, can itself produce postoperative pulmonary complications in patients with healthy lungs, which worsen the patient's evolution and prognosis.

The causes that justify the appearance of these complications seem to be mainly related to the way the intraoperative mechanical ventilation is applied. In fact, different adjustments and ventilatory strategies such as recruitment maneuvers (strategies to maintain the full volume of the lung), the adjustment of positive pressure at the end of expiration and the maintenance of a certain level of pressure in the airway during the postoperative, have been shown to reduce the incidence of pulmonary and extrapulmonary complications and even mortality.
However, despite knowing their advantages, these strategies are not widely used in routine clinical practice. The reality is that there is a great variability between different

doctors and hospitals, in terms of how the adjustment of mechanical ventilation is performed in patients undergoing surgery, and also there are variations in the respiratory management that the patient receives after completing the intervention.
One possible reason for this lack of homogeneity when applying mechanical ventilation is that until now no clinical study has been done to determine which is the best fit and its correlation with the final outcome of the patients. For this reason, the present study is proposed (aquí he borrado unas palabras que lo único que hacían era dejar sin sentido la frase) to obtain the basis to influence the improvement of mechanical ventilation adjustment in the daily clinical practice of the surgical patient during anesthesia and the postoperative period.

What is the purpose of this study?
The objective of the iPROVE-OLV study is to determine whether a customized adjustment of mechanical ventilation for each patient during anesthesia versus a standard ventilatory management (equal for all patients), significantly decreases the occurrence of pulmonary and systemic complications during the first 30 days after surgery, readmissions not scheduled in the intensive care unit, hospital stay as well as in-hospital mortality.

Why have you been asked to participate?
You have been asked to participate in this scientific research study, because you will undergo surgery on your lungs under general anesthesia and artificial ventilation, and when you leave the operating room it is expected to stay a few hours in the Post-Anesthesia Recovery Unit (PACU). In this study, 1350 patients from different Spanish hospitals will be included. Because it is not known which of the different adjustments of mechanical ventilation is the best to reduce postoperative pulmonary and systemic complications, it will be assigned randomly (as if we were tossing a coin) to participate in one of the two study groups. Therefore, you have a 50% chance of receiving any of the adjustments.

What does your participation consist of? What type of tests or procedures will be performed?
The start of participation in the study is the day of your surgery. Before starting the study, your personal medical and surgical history, your clinical situation, and the results of the most recent tests performed during the preanesthesia visit will be reviewed to determine if you meet the criteria to participate in the study. If you meet the criteria and decide to participate, you will be randomly entered into one of the two possible treatment groups:
Group 1: Standard intraoperative and postoperative ventilatory adjustment (the most commonly used for all patients).

Group 2: Customized intraoperative and postoperative ventilatory adjustment.
During the duration of general anesthesia and during admission to the Post-Anesthesia Recovery Unit, data related to the intervention itself and to the manner in which the ventilator settings are scheduled during anesthesia will be collected. Respiratory and circulatory function data will also be recorded by various monitors usually used for this purpose, and by means of the analysis of arterial blood samples.
We will also assess the occurrence of complications of any kind during the 7 days following the intervention, and 30 days after surgery we will be interested to know if you have had any type of complication, if you are still in the hospital or if you have already received the high to your house.
It is possible that other complementary tests could be performed during the study, if indicated (blood test, chest x-ray, electrocardiogram ...). None of these tests is going to be a risk to you. All these determinations will be made by the investigating doctor or the person of the team designated by him.
It is important that you know that your participation in the study does not imply alteration of the treatment you are taking (if you have it) and any treatment that can be done from the clinical-biochemical studies that are performed will always be under medical criteria.

What are the general risks of participating in this study?
No risk is anticipated other than usual during any general anesthesia in which open lung maneuvers are applied. The most frequent complication when these maneuvers are applied is the drop in blood pressure that is treated either by increasing the speed of the liquids administered by the dropper, or with specific medications.

What are the benefits of participating in this study?
Based on previous knowledge and observations it seems that the application of mechanical ventilation in a personalized way can reduce the appearance of postoperative complications, however, we cannot guarantee that you will obtain direct clinical benefits for your participation in the study, since that is precisely what we want to find out. In any case, your participation will help to better understand the outcome of different ventilation strategies and thus improve the prognosis and treatment of future patients.

What will happen if I decide not to participate in this study?
Your participation in this study is totally voluntary. If you decide not to participate in the study, this will not change the treatment and monitoring of your disease done by your doctor or the rest of the caregivers who take care of your illness. Likewise, you may withdraw from the study at any time, without having to give explanations.

Alternative clinical management

The alternative to enter this study is to receive mechanical ventilation with the usual adjustment that may or may not include the maneuvers proposed in this study.

Who can I ask in case of doubt?

It is important that you discuss with any of the investigators of this project the details or doubts that arise before signing the consent for your participation.

Likewise, you can request any explanation that you wish about any aspect of the study and its implications throughout the same by contacting the principal researcher of the center.

Confidentiality:

The data obtained from your participation in the study will be treated according to the national regulation on data protection (Organic Law 15/1999 on the protection of personal data). Your data will be incorporated into a computerized database so that the information obtained cannot be associated with an identified or identifiable person. Equally, in the publication of the results, there won't be any moment in which personal data of patients who have collaborated in this investigation will be leaked.

No data will be accessible to any person who is not part of the team of this study except that the information collected could be reviewed by professionals dependent on the Health Authorities, members of the Clinical Research Ethics Committee, monitor of the study, and other persons designated by the Law to verify that the study is being carried out correctly.

As contemplated by the Law on Protection of Personal Data, you can exercise your right to access, rectify, cancel or oppose your data by contacting the principal investigator of this study.

Other relevant information

During your participation in this study, blood samples will be taken from an arterial catheter during the surgical procedure and in the period after the intervention. Part of the blood sample will be analyzed immediately after its extraction and another part will be stored together for its later analysis once the study is finished. What may remain will be eliminated immediately. This sample will always be used for scientific purposes.

INFORMED CONSENT

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Principal investigator: Carlos Ferrando Ortolá
Department: Anesthesiology
NTC:
Sponsor: Dr. F. Javier Belda.

I, _____ have been informed by Dr / Dr. _____, collaborator of the aforementioned research project, and I declare that:

- I have read the Information Sheet that has been given to me
- I was able to ask questions about the study
- I have received satisfactory answers to my questions
-I have received enough information about the study

I understand that my participation is voluntary
I understand that all my data will be treated confidentially
I understand that I can withdraw from the study:
-Whenever you want
- Without having to explain
- Without this having an impact on my medical care
With this I give my consent to participate in this study,

Signature of the patient:
Date:

Signature of the Investigator:
Date