INFORMED CONSENT

PARTICIPANT No.. _____ out of a total of 206

PROJECT TITLE: "COMPARISON OF THE EFFECTIVENESS OF NON-INVASIVE VENTILATION WITH A FACE MASK IN ADULT PATIENTS UNDERGOING GENERAL ANESTHESIA: TWO-HANDED C-E VENTILATION TECHNIQUE VS TWO-HANDED V-E VENTILATION TECHNIQUE*"*

Site where the study will be conducted: Surgery Service, Alma Mater Hospital of Antioquia

Entities supporting the research: Alma Mater Hospital of Antioquia, Perioperative Medicine Research Group, Faculty of Medicine, University of Antioquia

Entity sponsoring the research: Perioperative Medicine Research Group, Faculty of Medicine, University of Antioquia

Introduction

On behalf of the Perioperative Medicine Research Group of the Anesthesiology Section of the Department of Surgery of the Faculty of Medicine of the University of Antioquia, we inform you through this document that you are invited to voluntarily participate in a study that seeks to identify the most effective technique for two-handed face mask ventilation, between the V-E and C-E maneuvers. In accordance with the guidelines set forth in Resolution No. 8430 of 1993 of the Colombian Ministry of Health and the 2013 Helsinki Declaration regarding the ethical aspects of health research with human beings, this is considered a type C investigation: research with greater than minimal risk.

Two noninvasive airway management interventions will be performed. These interventions are part of the anesthesiologist's daily practice and seek to improve the effectiveness of noninvasive pulmonary ventilation with a two-handed face mask, a practice that is increasingly important in difficult airway situations.

The principal investigator of the study believes that you meet the criteria to be included in the study, which are: over 18 years of age, scheduled for elective surgery, require general anesthesia andconsentparticipation in the study.

It is emphasized that the study will not change the routine care and management of patients undergoing surgery, nor will it change the intraoperative care. The only change will be the face mask ventilation technique after anesthesia induction.

Purpose

To determine whether the V-E technique is superior to the C-E technique for two-handed facemask ventilation in adults undergoing general anesthesia, while also defining the mean end-expiratory CO2 in mmHg, proportion of ineffective ventilation, mean ventilation in milliliters, operator satisfaction, and perceived ease of use. The following protocol is described:

Selection of participants

Based on previously established inclusion criteria, and after the patient agrees to participate, we will randomly select the two face mask ventilation techniques we will be comparing.

Type of intervention

If you wish to take part in the study, the study and its purpose will be explained to you on the day of your surgery. You will be randomly assigned to one of the two comparison groups: V-E face mask ventilation maneuver or C-E face mask ventilation maneuver..Once you arrive in the operating room, your vital signs will be fully monitored. Beforehand, the anesthesia machine will be checked for normal operation. During the procedure, a device called an oropharyngeal cannula will be inserted, which will be sized to fit your size, as will the face mask that is attached to your face. You will be instructed to breathe actively and deeply into the face mask. You will then be given medications, which will put you to sleep. Afterward, the anesthesiologist will perform ventilation with the face mask, and the researcher will collect the necessary data for the study.

Voluntary participation

Please note that your decision to participate is voluntary, meaning you are free to accept or decline participation in the study. You may withdraw at any time without explanation and without incurring any penalties. Additionally, the research group is available to explain any terms you may not understand and to answer any questions you may have.

If you decide not to participate in the study, this will not have any repercussions on your surgical and anesthetic treatment, which will continue normally without major setbacks as initially planned.

Duration

The study will last approximately 24 months. After the intervention is received and airway management is defined with a different device, either a laryngeal mask or an endotracheal tube, no follow-up will be performed.

Risks and inconveniences

By participating in this research, you will be exposed to the risks associated with each ventilation technique, which are no different from those associated with standard noninvasive ventilation. These risks include: bronchoaspiration, laryngospasm, bronchospasm, hypoxemia, and hypercapnia; and with the use of an oropharyngeal airway, dental trauma (tooth loss, tooth fracture), oral trauma, and bleeding, which generally have a low incidence. The benefits of providing adequate pulmonary ventilation while ensuring adequate oxygenation. If you experience any adverse effects, you will be monitored and treated by the attending anesthesiologist, who will determine the appropriate management.

Benefits

The main benefit of the study is to generate knowledge that could impact healthcare teams

and, consequently, the outcomes of future patients. At the same time, you will enjoy improved ventilation, thereby reducing the incidence of hypoxemia, and anesthesiologists will gain insight into the best technique and which could impact airway rescue scenarios. No financial incentives will be given to you or your family.

Confidentiality

Your participation data will be protected and treated confidentially under a code that identifies each case without identifying you personally. At no time will any data or results that could prove your participation be published; however, the Medical Regulatory Authorities and the Ethics Committee may request your records if necessary, always ensuring compliance with professional secrecy.

Participant's obligations

There are no obligations for you to participate in this study; your only commitment is to authorize the use of relevant data for the research.

Obligations of the researcher

1. Collect data derived from the intervention in an organized and relevant manner.

2. Be aware of and resolve any problems that arise during the study period.

3. Answer and clarify any questions about the procedures, risks, benefits, and other matters related to the research.

4. Request evaluation by the respective specialists or services you need that arise from the anesthesia performed.

5. Keep patient data hidden from personnel not involved in the research, i.e., confidentiality.

6. The research was duly approved by the ethics committee of Alma Mater Hospital in Antioquia. The researchers are physicians with current medical degrees from certified universities, and the treating anesthesiologists are certified in their specialty by the Ministry of Social Protection.

7. Disclose the results of the investigation once it is concluded.

Complications arising from the surgical procedure will be covered by each patient's healthcare provider, as is customary. This is because there is no intention to modify the patient's proposed surgical procedure.

Signing this document does not imply a waiver of any legal rights that may apply.

Expected results

The results will be published in a journal that will be accessible nationally and/or internationally. Dissemination of the results will lead to widespread use of these techniques in

the general population, with benefits and reduced risks.

Questions

Before signing this document, you should read it completely and ask the research team questions until you are satisfied with the answers. If you have any questions later, you can contact the principal investigator, Dr. Aldair Sayed Vides Villamizar, at 3017492294.

Before signing, please answer the following questions:

DATE: Day _____ Month _____ Year _____

-Have you been informed about the study by the research group? ___
-Have you read and understood the entire document? ___
-If you had any questions, were all your questions answered? ___

PARTICIPANT:

Acceptance of participation in the Study

I, _____, with citizenship card number _____ of _____, confirm that I have read, that the information for the above study has been explained to me, and that I have had the opportunity to ask and have had any questions answered. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any explanation, without affecting my medical care or legal rights. I understand that the study researchers, the institutional ethics committee, and judicial authorities will be the only people who may observe my health records. I agree to the collection, processing, reporting, and transfer of data collected during this study to the location determined by the researcher in charge and that these data may only be used for this research.

RESEARCHER:
The details of the study, the purpose of the study, the methodology, its benefits, risks, duration, and any questions were answered to the participant.

_____

Name and surname of the researcher Signature

ID: _____ Medical record: _____

WITNESS 1:

_____

Name and surname of the witness Signature

Ballot: _____

WITNESS 2:

_____

Name and surname of the witness Signature

Ballot: _____