COVER PAGE INFORMED CONSENT FORM

Official title:

Does it worth to reinforce with additional anesthesia to improve postoperative course after orthognatic surgery?”

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Title of the investigation: "Does it worth to reinforce with additional anesthesia to improve postoperative course after orthognatic surgery?".

The investigators have requested your participation in a research study. Before deciding if you agree to participate, it is important that you understand the reasons why the research is being conducted, how your information will be used, what the study will consist of and the possible benefits, risks and discomforts that may result. In the case of participating in any other study, you must inform the person responsible to assess if you can participate in it, since a patient can only participate in a study.

Background and current status of the subject: **"Does it worth to reinforce with additional anesthesia to improve postoperative course after orthognatic surgery?".**

Shortly, you will undergo a maxillofacial surgery that requires postoperative pain control at a multidisciplinary level by the Anesthesiology team and the Maxillofacial Institute of Teknon Medical Center. It is proposed to participate in a comparative study where no usual practice of the surgical procedure is changed or the postoperative period is lengthened. Patients will be assigned to two groups randomly to receive different pharmacological measures to reduce postoperative pain.

For the control of pain, a multimodal approach is recommended, and the use of local anesthetics is essential. We propose the use of local anesthetics applied by the titular surgeon in two stages, first pre-incisional (once the patient is under general anesthesia, before beginning the surgical approach) and second

postoperatively before awakening the patient, for better control of postoperative pain.

Bimaxillary osteotomy is a frequent and potentially painful surgery in adults. Bimaxillary surgery under general anesthesia is the common practice. And isolated peripheral nerve blocks are widely used. These minor blockages are used to avoid the undesired effects of anesthetics and analgesics; particularly the adverse respiratory effects of opioids. The practice of loco-regional anesthesia therefore provides a control of perioperative pain in a multimodal manner showing effective postoperative analgesia and minimizing respiratory depression due to excess opioid use.

For bimaxillary surgery, pre-incisional infiltrations are performed by the same surgeon to block isolated peripheral nerves (maxillary and mandibular intraorally and intranasally). In general, the choice of local anesthetic (LA) is influenced by considerations such as the onset of action, duration and toxicity. We propose infiltration in two times before and after surgery with two different ALs to optimize the control of postoperative pain. We avoid the use of a combination of AL in a single infiltration. On the other hand, with two-stage infiltration with two different LAs (pre-incisional with lidocaine and pre-extubation with ropivacaine) we obtained the advantages of a rapid onset of lidocaine, and a prolonged effect of ropivacaine for greater control of postoperative pain for a longer period. The control of postoperative pain is a primary factor to achieve greater patient satisfaction, better rehabilitation and shorter hospital stay. The current clinical guidelines recommend the management of postoperative pain control in a multimodal manner; and this includes the use of local anesthetics.

The purpose of the study

To determine whether the performance of an infiltration with local anesthetic before the patient's awakening reduces postoperative pain and improves patient comfort in the first 18 postoperative hours.

Do I have an obligation to participate?

The decision about whether or not to participate in the research study is yours. In the case of not wanting to participate or of wanting to leave this study, the quality of the assistance you will receive will not be affected and the usual medical protocols will be followed. If you decide to participate, you will be given the informed consent document to sign.

What will happen if I agree to participate?

The scientific team of the present study will analyze and collect the data referring to the surgery that you have received. To assess the effectiveness of local anesthetic infiltration before awakening it will be necessary to assess the following parameters:

- Pain registration in the first postoperative 18 hours
- Registration of the administration of opioid drugs in the first postoperative 18 hours
- Registration of nausea and vomiting in the first postoperative 18 hours
- Compilation of adverse effects

What are the possible adverse effects, risks and discomforts associated with participation?

The surgical and operative procedures are the same regardless of their participation in the study:

- General anesthesia
- Infiltration of local anesthetic
- Orthognathic surgery

What are the possible benefits of participating?

To help the scientific community to determine if infiltration with local anesthetic after orthognathic surgery prior to postoperative awakening improves patient comfort in the first 18h after being operated on.

How will my data be used in the study?

This will be adjusted according to the provisions of Organic Law 15/1999, of December 13, on the protection of personal data (LOPD), in force in Spain and for which they specify the ARCO rights (access, rectification, cancellation and opposition). of personal data. The study doctor will use your personal data for the administration and direction of the study, research and statistical analysis.

How can I establish contact if I need more information or help?

By signing this form, you agree that you have been informed of the characteristics of the study, have understood the information and the doctor has clarified all your doubts. In case of suffering a damage related to the study or to obtain an answer to any question that may arise during the investigation, please contact the persons responsible for the study: Dr Hernández-Alfaro, Dra Valls and Dra Gloria Molins at the Maxillofacial Institute Quiron-Teknon.

INFORMED CONSENT

Me, Mr./Mrs./Miss: ……..

- I have received verbal information about the study and have read the attached written information, from which I have received a copy.
- I have understood what has been explained to me.
- I have been able to comment on the study and ask questions of the responsible professional.
- I give my consent to take part in the study and I assume that my participation is totally voluntary.
- I understand that I may withdraw at any time without affecting my future medical assistance.
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By signing this informed consent form, I give my consent so that my personal data can be used as described in this consent form, which complies with the provisions of Organic Law 3/2018, of December 5, of Protection of Personal Data and guarantee of digital rights. "It is the adaptation to the Spanish legal order of Regulation (European Union) 2016/679 of the European Parliament and the Council of April 27, 2016

I understand that I will receive a copy of this informed consent form.

Signature of patient Date

Identification Document (ID) number

DECLARATION BY THE INVESTIGATOR

The patient or patient signing this consent form has received, on the part of the professional, detailed information in oral and written form of the process and nature of this research study, and has had the opportunity to ask any questions regarding the nature , the risks and benefits of your participation in this study

Signature of investigator Date

Gloria Molins MD, MSc