PATIENT INFORMATION SHEET

"Clinical trial for the effectiveness of pudendal nerve block with and without neurostimulation for the reduction of posthemorroidectomy pain"

PRINCIPAL INVESTIGATOR
Ana Soto Sánchez
General and Digestive System Surgery 7th floor central building HUNSC
Contact phone number: 922602075/ 922601981

CENTER:
Nuestra Señora de Candelaria University Hospital

INTRODUCTION
We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the corresponding Research Ethics Committee.
Our intention is only that you receive correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To this end, please read this information sheet carefully and we will clarify any doubts that may arise after the explanation. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION
You should know that your participation in this study is voluntary and that you can decide not to participate or change your decision and withdraw your consent at any time, without altering the relationship with your doctor or causing any harm to your treatment.

GENERAL DESCRIPTION OF THE STUDY:
Hemorrhoidal pathology is one of the main reasons for consultation in coloproctology units. Conventional hemorrhoidectomy continues to be the Gold Standard of surgical treatment, although with a not inconsiderable percentage of postoperative pain despite the armamentarium currently available.

The pudendal nerve block with local anesthetic is an effective alternative for pain control in some urological and gynecological procedures, in pain medicine and is routinely performed in proctological procedures in our center. However, numerous studies have described a great anatomical variability of this nerve, which may mean that infiltration according to anatomical references may sometimes be ineffective.
The present study aims to compare the efficacy of pudendal nerve block with local anesthetic guided by anatomical landmarks or guided by neurostimulation (system that allows localizing a nerve through a small electrical stimulation).

The study will be carried out in the Colorectal Surgery Unit of the General and Digestive Surgery Service of the Hospital Nuestra Señora de Candelaria. Patients with suspected hemorrhoidal pathology will be evaluated in general and digestive surgery as usual.

Those patients with indication for hemorrhoidectomy will be included in the surgical waiting list according to the usual criteria, evaluating symptomatology, examination, response to conservative treatment and complementary tests if necessary, as it was done previously.

Once included in the waiting list, they will have a second consultation prior to the intervention. The principal investigator or her research team will inform the patient of the study and offer to participate in it. If the patient accepts, he/she will sign the informed consent form. After this, a standardized clinical history will be taken and the patient will await the date of the operation after a pre-anesthetic assessment for surgery in AMC.

The surgery will be performed according to the Ferguson technique in all patients by some of the surgeons of the colorectal surgery team, and after completing the intervention, a randomized decision will be made as to whether the patient belongs to the pudendal nerve infiltration group guided only by anatomical references or guided by neurostimulation.
A total of around 86 patients are expected to be included.

COLLECTION OF BIOLOGICAL SAMPLES:
The present study does not require obtaining biological samples.

CONFIDENTIALITY
The processing, communication and transfer of personal data of all participating subjects will comply with the provisions of the Organic Law 3/2018 of 5 December on the Protection of Personal Data and guarantee of digital rights, and the application of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (GDPR), so it is important that you are aware of the following information:
- In addition to the rights you already know (access, modification, opposition and cancellation of data) you can now also limit the processing of data that are incorrect, request a copy or that the data you have provided for the study be transferred to a third party (portability). To exercise your rights, please contact the principal investigator of the study. We remind you that the data cannot be deleted even if you stop participating in the study in order to ensure the validity of the research and to comply with legal duties and drug authorization requirements. You also have the right to contact the Data Protection Agency if you are not satisfied

- The Center as well as the Sponsor and the Investigator are respectively responsible for the treatment of your data and are committed to comply with the data protection regulations in force. The data collected for the study will be identified by a code, so that no information that can identify you is included, and only your study physician/collaborators will be able to relate such data to you and your medical history. Therefore, your identity will not be disclosed to any other person except to health authorities, when required or in cases of medical emergency. The Research Ethics Committees, the representatives of the Health Inspection Authority and the personnel authorized by the Sponsor will only have access to check the personal data, the clinical study procedures and the compliance with the standards of good clinical practice.
compliance with the standards of good clinical practice (always maintaining the confidentiality of the information).

The Investigator and the Sponsor are obliged to keep the data collected for the study for at least 25 years after its completion. Thereafter, your personal information will only be retained by the Center for your health care and by the Sponsor for other scientific research purposes if you have given your consent to do so, and if permitted by applicable law and ethical requirements.

ADDITIONAL INFORMATION
As required by law, you must sign and date the informed consent form to participate.
The principal investigator of this study at this center is Dr. Ana Soto Sánchez.

If during the course of this study you have any questions related to the study, you may consult with Dr. Soto of the General Surgery Service of the Hospital Universitario Nuestra Señora de Candelaria.

INFORMED CONSENT

I (name and surname)

.....

I have read the information sheet given to me. I have been able to ask questions about the study. I have received sufficient information about the study.

I have spoken to:

..... ……

(name of investigator)

I understand that my participation is voluntary. I understand that I can withdraw from the study:

1- Whenever I want
2- Without having to explain myself.
3- Without any repercussions on my medical care.

I freely give my agreement to participate in the study and consent to the access and use of my data under the conditions detailed in the information sheet.

Signature of the patient: Name:
Date:

Investigator's signature: Name:
Date: