Is WALANT Applicable in Distal Radius Fracture Osteosynthesis?

Patient's informed consent document

October 2020

NCT (still not available)

PATIENT'S INFORMATION DOCUMENT

PROJECT TITLE: Is WALANT applicable to distal radius fracture osteosynthesis?

1. Introduction

We are writing to inform you of the clinical trial in which you are invited to participate. It is our intention that you receive the correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this trial. Read this fact sheet carefully and we will clarify any doubts that may arise after the explanation. In addition, you can consult with the people you deem appropriate.

2. Voluntary participation

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

3. Study overview

In this hospital we are conducting a prospective randomized study with the aim of knowing and assessing the benefits of LANT anesthesia (Local Anesthesia No Tourniquet) compared to conventional anesthesia using the ischemia sleeve, in the osteosynthesis of fractures of distal radius, ie in the surgical treatment of this type of fracture.

The WALANT technique (Wide Awake Local Anesthetic No Tourniquet) is an anesthetic modality that consists of the progressive and regional administration of local anesthesia combined with adrenaline in the fracture area (in the wrist in our case). This technique allows the administration of a long-lasting anesthetic locally but combined with a vasoconstrictor that makes it easier for us not to bleed during the operation. This way we can replace the use of the ischemia sleeve (the same one with which we measure our blood pressure).

The conventional technique requires the use of the ischemia cuff and the administration of locoregional anesthesia with blockage of the entire extremity as the cuff is placed in the proximal part of the arm. This technique is also conditioned by the time given that the cuff cannot be used for more than two hours in a row to prevent damage to the bloodless tissues. In this case, the guidelines of the Anesthesia Service will be followed, of which you will also be informed and sign your specific informed consent.

In both groups, the need for sedation or not will be assessed in order to offer better patient comfort during the intervention.

Walant technique is a safe and effective anesthetic method as the administration is at the subcutaneous level and around the bone but avoiding the administration to the bloodstream in order to avoid the cardiovascular, neurological and respiratory effect.

Possible specific adverse effects from the use of the drugs used in the WALANT

technique are:

- At the cardiovascular level, decreased heart rate and hypotension.

- Signs of toxicity such as tremor, dizziness, blurred vision, hearing buzzing and drowsiness may appear in the central nervous system.

- Hypersensitivity reactions (allergic reaction).

- Degeneration of the cartilage of the joint.

- At the respiratory level it has been associated with respiratory arrest events.

Two groups of patients will be created and each will be assigned to one of the two techniques described above. You will be included in one group or another at random, that is, randomly.

If you agree to participate in the study, you will be interviewed before surgery, 24 hours after surgery, a visit to the treatment (7-10 days) and one month after surgery.

This study is linked to the Orthopedic Surgery and Traumatology Service of the Arnau University Hospital in Vilanova de Lleida and its managers are Dra. Prats, Dra. Scott and Carla Albert (Medical Student at the University of Lleida). Contact telephone number for researchers: 973705293 4.

4. Confidentiality

The processing, communication and transfer of personal data of all participating subjects will comply with the provisions of the data protection regulations, Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights.

In accordance with the provisions of the aforementioned legislation, you can exercise the rights of access, modification, opposition and cancellation of data, so you must go to the doctor in charge of the study. The data collected for the study will be identified by a code and only the doctor in charge of the study or collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be disclosed to any person except in exceptional cases, in case of medical emergency or legal requirement.

Only the data collected for the study will be processed by third parties and other countries, which in no case must contain information that can directly identify it, such as name and surname, initials, address, social security number, etc. In the event that this transfer occurs, it will be for the same purposes of the study described and guaranteeing confidentiality at least with the level of protection of the legislation in force in our country.

Access to your personal information will be restricted to the study doctor, collaborators, health authorities (Spanish Agency for Medicines and Health Products), Clinical Research Ethics Committee and staff authorized by the promoter,

when they need to check. the data and procedures of the study, but always maintaining the confidentiality of the same in accordance with current legislation. Access to your medical history should be limited to the study.

Date:

Patient's signature:

Researcher's signature:

PATIENT'S INFORMED CONSENT DOCUMENT

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Mr/Ms/Miss ……. with DNI number ....., I authorize the researchers and doctors from the Traumatology Service of the Arnau de Vilanova University Hospital to use my clinical data anonymously under the directives of the Data Protection Act.

Date:

Patient's signature:

Researcher's signature: