1. COVER PAGE

1. Official title:

Informed consent form of the study (ID: POF-LEV-2019-01): a retrospective clinical registry of peripheral nerve block

2. NCT number:

NCT04451642

3. Document date:

20th May 2020

PATIENT INFORMATION SHEET

Protocol code	**POF-LEV-2019-01**
Center	**Department of Anesthesiology, Reanimation and Pain Management. University Hospital Miguel Servet. Zaragoza. Spain.**

1.

INTRODUCTION:

It is our pleasure to **invite you to participate in a study we are about to begin.** The study has been approved by the Drug Research Ethics Committee of the hospital and by the Spanish Agency for Medicines and Health Products (AEMPS), in accordance with Spanish Royal Decree 1090/2015 of 4 December and European Regulation 536/2014/EEC of 16 April, which regulate the performance of drug-based clinical trials.

Our goal is to provide you with enough detailed information to allow you to **decide whether you would agree (or decline) to participate in the study**. You are requested to read this information sheet carefully and get back to us in case you have any doubts or queries.

Needless to say, you may consult with as many people as you deem appropriate prior to making your final decision.

2. YOUR PARTICIPATION IS VOLUNTARY

We are inviting you to participate in this study because **you are due to be undergo regional anesthesia block at the Department of Anesthesia, Reanimation and Pain Management in the University Hospital Miguel Servet (Zaragoza, Spain).**

Please be advised that your participation in this study would be **voluntary** and you may decide **NOT** to participate. Should you decide to participate, you may change your mind and withdraw your consent at any time, without this affecting your relationship with your doctor and without any prejudice to your treatment.

Agreeing to participate in this study means giving your consent to being examined by ultrasounds and spirometry and granting us access to your hospital medical records.

3. PURPOSE OF THE STUDY

The research is motivated by the high number of peripheral nerve blocks that our department performed during orthopaedic surgeries. Our hypothesis is that our routine practice is safe.

The main goals of the study are to assess the peripheral nerve blocks performed and their safety during our routine clinical practice.

4. STUDY DESCRIPTION

This research is a descriptive, observational, retrospective, single-center, retrospective study of a population-based sample of all patients who have undergone orthopedic and trauma surgery and who have undergone PNB, according to standard clinical practice, in the Traumatology Anesthesia Unit of the Miguel Servet University Hospital (Zaragoza, Spain).

The drug administered will be local anesthetic such as:

- Levobupivacaine 1.25 mg/ml Solution for Injection and for infusion.
- Levobupivacaine 2.5 mg/ml solution for injection and infusion.
- Levobupivacaine 5 mg/ml solution for injection and infusion.
- Mepivacaine 1% Solution for Injection EFG.
- Mepivacaine 2% Solution for Injection EFG.
- Bupivacaine Hyperbaric 1.25 mg / ml solution for injection.
- Bupivacaine Hyperbaric 2.5 mg / ml solution for injection.
- Hyperbaric Bupivacaine 5 mg / ml solution for injection.
- Lidocaine 20 mg / ml solution for injection.

The study does not require subjects to fill out any questionnaires. Nor do they have to make any additional hospital visits or provide any biological samples.

5. POTENTIAL BENEFITS

As the study will be geared toward the generation of knowledge, it is not likely that your participation will result in any benefit for your health. However, by participating you will be contributing to furthering scientific knowledge and promoting social wellbeing.

You will not receive any economic compensation for enrolling in the study. You will nevertheless incur no economic expense as a result of your participation.

6. INSURANCE

In accordance with the applicable legislation (Royal Decree 1090/2015) the public hospital activity is under insurance policy that provides for compensation to be awarded to subjects in case of harm and/or injury caused as a result of the routine clinical practice.

7. PERSONAL DATA PROTECTION

Data protection Regulation (EU) 2016/679 of the European Parliament and of the Council (GDPR) of 27 April 2016 has been in force since 25 May 2018. For that reason, you must be aware of the following:

- In addition to the rights you are already familiar with (access to, rectification of, objection to and cancellation of data) you can now limit the processing of erroneous data, request a copy of any of your personal data being processed or ask for your data to be transferred to a third party (portability). To exercise your rights under the GDPR, please contact the Principal Investigator or the Data Protection Officer of the hospital at www.iisaragon.es .Please note that, even if you decide to drop out of the study, your data cannot be erased as this would impact the validity of the findings and prevent us from complying with our legal requirements and the medication authorization procedures. Should you have any objections, you can contact the Data Protection Agency.
- Both the Hospital and the Promoter of the study are responsible for the processing of your data and undertake to abide by the applicable data protection regulations. The data collected for the purposes of the study will be coded so that it cannot be traced back to any individual patient. Only your doctor and/or the researchers participating in the study will be able to connect your data with your clinical record. This means that your identity will not be disclosed to anybody, except to the health authorities if requested or in case of a medical emergency. Research ethics committees, health inspectors and the Promoter (personally or through persons authorized by them) will only be allowed access to the data repository to check personal data, review the procedures under the clinical trial, and ensure compliance with clinical best practices. They are strictly required to preserve the confidentiality of the information.
- The principal Investigator and the Promoter are obliged to preserve the data collected for the trial for at least 25 years following its completion. After that, your personal data will only be maintained at

the hospital for use in connection with your healthcare. Should the law and the applicable ethical requirements allow it, the Promoter may keep your data for use in other investigational projects with your explicit authorization.

- Should any of your coded data be transferred to entities in our group, to service providers or to scientists that may collaborate with us from outside the EU, such data will be protected by the data protection authorities by means of safeguards such as contracts or other mechanisms. For more information, please contact the Promoter's Data Protection Officer at www.iisaragon.es

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INFORMED CONSENT FORM

I, ... *(subject's name and surname)*

☐ Have read the patient information sheet that was delivered to me

☐ Have been given the opportunity to ask questions about the study.

☐ Have received enough information about the study.

☐ Have spoken to *principal investigator)*

☐ Understand that my participation is voluntary.

☐ Understand that I can withdraw from the study:

1) Whenever I wish to do so

2) Without giving any explanations

3) Without this affecting the care I receive

I will receive a signed and dated copy of this informed consent form

I freely give my consent to participate in the study.

……. ……..

Subject's signature Investigator's signature

Date: ____/____/_____ Date: ____/____/_____

(Name, signature and date in the subject's own handwriting)

(To be filled out when informed consent is obtained from **differently abled persons)**

…… ……..

Signature of legal guardian, family representative or civil partner

Investigator's signature

Date: ____/____/_____

Date: ____/____/_____

I wish to be informed about any data arising from the investigation that may be relevant to my health:

☐ YES

☐ NO

…… ……

Subject's signature

Investigator's signature

Date: ____/____/_____

Date: ____/____/_____

WITNESSED INFORMED CONSENT FORM

I, ... *(witness' name and surname), acting as a witness,* declare that Mr/Mrs …….....(name and surname of the subject) has in my presence been given and read the patient information sheet concerning the present study in such a way that:

☐ He/she has been able to ask questions about the study.

☐ He/she has received enough information about the study.

☐ He/she has spoken to *principal investigator)*

☐ He/she understands that his/her participation is voluntary

☐ He/she understands that he/she may withdraw from the study

1) Whenever he/she wishes to do so

2) Without giving explanations

3) Without this affecting the care he/she receives

I will receive a signed and dated copy of this informed consent form.

……. ……..

Subject's signature Investigator's signature

Date: ____/____/_____ Date: ____/____/_____

(Name, signature and date in the witness' own handwriting)

The patient wishes to be informed about any data arising from the investigation that may be relevant to their health:

☐ YES

☐ NO

…… ……

Witness' signature Investigator's signature

Date: ____/____/_____ Date: ____/____/_____

☐ The subject cannot read or write.

☐ A member of the study staff has read the document to and reviewed it with the subject, giving the latter the chance to ask questions or consult with other people.

☐ The witness must be an impartial person, unrelated to the study.