INFORMATION SHEET AND INFORMED CONSENT

Title:	**Randomized and controlled Phase IV clinical trial on the analgesic efficacy of the combined block (PENG -pericapsular nerve group) and the femoral lateral cutaneous nerve in hip fractures of the elderly. Comparative study between levobupivacaine and ropivacaine**
Code:	**PENG-CAD**
EudraTC No.	**2020-004697-21**
Version:	**1.0 of 1 September 2020**
Promoter:	**Biomedical Research Institute of Salamanca (IBSAL)**
Principal Investigator	**Agustin Diaz Alvarez**

Introduction

We approach you because you have fractured your hip, to inform you about a clinical trial in which you are invited to participate. You should know that your participation in this study is voluntary and that you may choose not to participate. Please take the time you need to read the following information and refer to what you want. Ask the researcher in this study if there's anything that's not clear to you or if you want to learn more.

Objective of the study

The objective of the study is to find the effectiveness in pain control of two local anesthetics (levobupivacaine and ropivacaine) through a technique in which painkillers are injected directly into the area surrounding the hip joint and into a nerve (the femoral) whose irritation from fracture and surgical manipulation produces pain.

This research study has been approved by the Ethics Committee of Research with Medicines of Salamanca, and is carried out in accordance with current legislation, Royal Decree 1090/2015 of December 4 and European Regulation 536/2014 of April 16, which regulates clinical trials with medicines.

Study procedures and possible risks and discomfort

This clinical trial will be held at the University Care Complex of Salamanca, and a total of 108 patients over 65 years of age who have fractured their hips and are going to be operated on will participate. Half of the patients will receive one of the study drugs (levobupivacaine) and the other half the other drug (ropivacaine). The assignment to each treatment group will be made randomly, which means that the decision on the local anesthetic used during the surgical process (levobupivacaine or ropivacaine) will be random. Both drugs are marketed and approved in our country for this indication, and are used in routine clinical practice since 2012 and 2013, respectively.

Participation in this study would not produce any additional discomfort to those of the surgical intervention to which you are going to be subjected. The side effects of the drugs under study are the same as those of other local anesthetics of the same class, especially nausea, vomiting and headache can occur. However, you should know that during the surgical intervention and in the postoperative period you will receive treatment to treat these side effects and others that

may appear during the intervention, in accordance with usual clinical practice. Being drugs approved by the competent health authorities, there is information available to everyone about the side effects of levobupivacaine and ropivacaine. Please speak with your study physician for a complete list of side effects reported with these drugs and in any case, if desired, you will be given the package leaflet for both medications.

The duration of the study will be from the signing of the informed consent until 48 hours after the surgical intervention.
Data will be collected on the efficacy to calm pain, the time it takes for medications to take effect, the duration of the same, and possible side effects, and scales and questionnaires will be carried out to assess pain at different times after the intervention, up to 48 hours after it. In addition, other data will be collected about you relevant to this research study, such as your weight, height, and constants during the surgical intervention and in the hours after.

In the present work, no biological samples are collected for research purposes, nor are procedures or tests carried out that are not part of routine clinical practice.

All information about this study will be stored encrypted, and will be used exclusively for the purposes specified herein. In the event that your data is transferred to other research groups, it will always be carried out in accordance with current legislation, keeping your data encrypted, to carry out studies related to the objectives of this work, and with the prior authorization of the Research Ethics Committee. In the event that the objectives of the research work proposed by other research groups are different from those of this project, a new consent will be requested.

Voluntary participation and withdrawal
You can freely decide whether or not you want to take part in this study, participation is entirely voluntary. If you decide to participate, you still have the possibility to withdraw at any time, without having to give explanations, and without any penalty or negative consequences for you. If you change your mind in relation to your data, you have the right to request its destruction or anonymization, through your doctor/researcher. However, you should know that the data that have been obtained in the analyses carried out up to that moment may be used for the requested purposes and may be kept in compliance with the corresponding legal obligations.

Possible benefits
You may not get any health benefits from participating in this study. However, the information obtained from this trial may contribute to medical advancement and could help other patients suffering from hip fracture in the future to better manage pain.

Alternative treatments
In case of not participating in the study, you will receive treatment according to usual clinical practice, and it is even possible that, if your anesthesiologist so decides, you will be able to receive the same drugs that are offered in this study. You may want to give the study doctor more information about alternative treatments.

Data protection and confidentiality
All information about your results will be treated strictly confidentially. Both the center and the promoter and the research team are responsible for the processing of their data and undertake to comply with the data protection regulations in force, currently Organic Law 3/2018, of

December 5, on the Protection of Personal Data and guarantee of digital rights and Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD). The data collected for the study will be identified by a code, so that no information that can identify you is included, and only the research team will be able to relate this data to you. Therefore, your identity will not be disclosed to any other person except to the health authorities, when required or in cases of medical emergency. The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, will only be able to access to verify the personal data, the procedures of the clinical study and the fulfillment of the norms of good clinical practice (always maintaining the confidentiality of the information).
Your data will be kept under the appropriate security conditions and it is guaranteed that the subjects cannot be identified through means considered reasonable by persons other than those authorized. The research team will analyse your data based on the legitimate interest of achieving the purposes of the study. The Investigator and the Sponsor are obliged to keep the data collected for the study for at least 25 years after its completion. Subsequently, your personal information will only be retained by the health care center and by the research team for other scientific research purposes if you have given your consent to do so and if permitted by applicable law and ethical requirements.

If the results of the study are susceptible to publication in scientific journals, at no time will personal data of the participants in this research be provided. We inform you that you have the right to access, rectify or cancel your data, and you can limit the processing of data that are incorrect, request a copy or transfer to a third party the data that you have provided for the study. To exercise their rights, or in case the participant wishes to expand information on the processing of their personal data, they may contact the main researcher of the study whose data are specified at the end of this document, the Data Protection Delegate of the Regional Health Management (dpd@saludcastillayleon.es) or our center (dpd.husa@saludcastillayleon.es). We remind you that data cannot be deleted even if you stop participating in the trial to ensure the validity of the research and comply with legal duties. You also have the right to contact the Data Protection Agency if you are not satisfied.

Information about results
In the event that you request it, at the end of the study and in accordance with article 27 of Law 14/2007 on Biomedical Research, you may be provided with information about the results of this research work.

I consent to the future use of the data that has been collected in the present research study to conduct other research related to the medical specialty or research area of this study.
□ YES □ NO

I consent to the future accessing my medical record again to collect data that is considered important for conducting other research related to the medical specialty or research area of this study.
□ YES □ NO

Contact details of the research team:

If you have any questions or need more information, please contact:

Name: **Dr. Agustín Díaz Álvarez**
Phone: **. 923 29 11 00 Ext 55483**

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

IBSAL

INFORMED CONSENT

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I *(First and Last Name)*

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I have read the information sheet I have been given about the study.

I have been able to ask questions about the study.

I have received enough information about the study.

I have read the information sheet that has been given to me

I have spoken with the Investigator

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I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1º Whenever you want

2º Without having to give explanations

3º Without having any negative impact

I voluntarily agree to participate in the clinical trial and authorize the use of all information obtained. I understand that I will receive a signed copy of this informed consent.

_____

Participant's signature Date

_____

Name and signature of the researcher date

_____

Signature of the legal representative, family member or related person in fact Date