Pulsed Epidural Radiofrequency Versus Epidural Steroid Injection in Patients with Failed Back Syndrome (EPIPUL Study)

NCT: pending assignment

March 2020

PATIENT INFORMATION SHEET (PIS)

Study Title:
Epidural Pulsed Radiofrequency versus Epidural Steroid Injection for Patients with Failed Back Surgery Syndrome: An Open-Label, Randomized, Multicenter Study

Study Code: EPIPUL
Sponsor: HM Hospitales Research Foundation
Coordinating Investigator: Dr. Agustín Mendiola de la Osa
Principal Investigator at Site:
Site:
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PLEASE READ THIS FORM CAREFULLY

Participation in this study is voluntary. You may choose not to participate or to withdraw at any time without affecting your usual medical care. No one can promise that this study will provide you with any benefit. Do not agree to participate until all your questions have been answered.

INTRODUCTION

You are being invited to participate in a clinical research study approved by the Clinical Research Ethics Committee of HM Hospitales University Hospital, in accordance with current legislation (Royal Decree 1090/2015 of December 4, and European Regulations 2017/745 and 2017/746). The purpose of this document is to provide you with accurate and sufficient information to decide whether or not to participate. Please read carefully and ask any questions you may have. You may also consult anyone you deem appropriate.

VOLUNTARY PARTICIPATION

Your participation is voluntary. You may withdraw your consent at any time without affecting your relationship with your physician or the quality of your medical care. You may also be withdrawn from the study by the sponsor or investigators for safety reasons, poor compliance, or other factors limiting your ability to contribute to the study objectives. In all cases, you will receive an explanation for your withdrawal.

BACKGROUND, OBJECTIVES, AND GENERAL STUDY DESCRIPTION

You have been invited to participate because you suffer from chronic back pain following failed back surgery. After several prior analgesic treatments with insufficient results, you are being offered a minimally invasive surgical technique to help alleviate your pain. Two different techniques, both proven safe and effective in previous studies and routine clinical practice, will be compared in this study to determine if one is superior.

Group 1: Lumbar Root Radiofrequency with Epidural Catheter (REC)

This technique involves introducing a needle into the epidural space near your spinal cord via a small puncture in the lower back at the sacral hiatus. After local anesthetic injection,

radiographic contrast is administered to visualize the nerve roots. A thin plastic catheter is guided under fluoroscopy to the target nerve roots. Once in position, pulsed radiofrequency is applied to the roots responsible for the pain. Medication may also be injected through the catheter before removal.

Group 2: Epidural Steroid Injection
This procedure is performed in the same manner as Group 1 but without electrical current application. Instead, a corticosteroid medication is injected to alleviate pain.

STUDY ACTIVITIES
The study lasts 6 months after surgery, with 124 participants (62 per group). Follow-up visits coincide with routine care visits. Each visit includes clinical evaluation and questionnaires on pain, quality of life, and satisfaction. Estimated duration: 20 minutes per visit.
Procedures per visit:
Selection: Pregnancy test, informed consent.
Baseline: ODI, SF-12, DN4 questionnaires.
Post-intervention: Pain VAS, ODI, SF-12, DN4, PGI-I at 1, 2, 4, and 6 months.

RISKS AND DISCOMFORTS
Possible risks include headache (rare), radicular pain, hematoma, epidural abscess, meningitis, and rare severe neurological injury. Risks from local anesthetics include temporary leg weakness; from steroids: localized pain, headaches, facial flushing, anxiety, insomnia, hyperglycemia, immunosuppression, gastric ulcers, avascular necrosis, cataracts.

POSSIBLE BENEFITS
Both treatments are routinely performed for chronic back pain after failed surgery. They are expected to be similar in safety and efficacy, though one may provide longer-lasting pain relief. Participation may not provide personal health benefit.

PREGNANCY
A pregnancy test is required at study entry. If pregnant, you cannot participate as anesthetics and corticosteroids may harm the fetus.

COSTS AND COMPENSATION
Participation will not incur additional costs.

INSURANCE
The sponsor has insurance coverage for any harm arising from study participation. Details available from the principal investigator.

CONFIDENTIALITY AND DATA PROTECTION
Study data will be stored securely and coded to protect your identity, in compliance with EU Regulation 2016/679 and applicable laws. Only authorized personnel may access identifiable information. Results may be published in scientific forums without identifying you.

INFORMED CONSENT

I have read and understood the information provided. I have had the opportunity to ask questions. I voluntarily agree to participate and allow the use of my data as described. I will receive a signed and dated copy of this consent form.

Participant's Name: Investigator's Name:

Investigator's Signature and Date: Participant's Signature and Date:

INFORMED CONSENT FORM FOR LUMBAR ROOT RADIOFREQUENCY WITH EPIDURAL CATHETER (REC)

First Surname: _____
Second Surname: _____
Name: _____
Date: _____ Medical Record No.: _____

DESCRIPTION OF THE PROCEDURE

The technique involves inserting a needle into an area of your spine called the epidural space, located near your spinal cord, through a small puncture in the lower part of your back at a point called the sacral hiatus. After the puncture, a local anesthetic is injected followed by radiographic contrast to visualize the anatomy of the nerve roots that exit the spine and extend to the extremities. A very thin plastic tube (catheter) is inserted and guided under fluoroscopic control to the nerve roots considered to be the cause of your pain. Once correctly positioned, a radiofrequency treatment (a special electrical current that blocks pain) is applied to the roots responsible for the pain through the same catheter, which can also be used to inject medication. The catheter is then removed. This is a minimally painful technique performed under aseptic conditions with local anesthesia. An X-ray machine is used to confirm correct catheter placement. Radiographic contrast must be used; therefore, if you have had allergic reactions to contrast agents or problems with radiological examinations, inform your physician. In a percentage of patients, this technique cannot be performed because it is not possible to locate the entry point for the needle.

TYPICAL RISKS

- Headache: Very rare. Usually occurs during the first few days after catheter placement and typically requires only analgesics and rest. In exceptional cases, a specific treatment may be required, such as a new lumbar puncture to perform a blood patch using the patient's own blood.
- Radicular pain during catheter placement due to irritation of a nerve root.
- Hematomas or bleeding at the puncture site in the back or in the epidural space where the catheter is located (very rare).
- Epidural abscess due to contamination from the skin (exceptional).
- Meningitis due to infection inside the nervous system from skin contamination.
- Complications related to the medications administered: local anesthetics may cause reversible muscle weakness in one or both legs; central nervous system injuries are exceptional but may cause loss of bladder and/or bowel control, leg weakness, and paralysis.

PERSONALIZED RISKS

These risks are related to the patient's pre-existing health conditions and the most significant ones include:

_____

_____

_____
_____

I DECLARE that I have been informed by the physician of the risks of lumbar root radiofrequency with epidural catheter, and I am aware that AT ANY TIME, I MAY WITHDRAW MY CONSENT.
I AM SATISFIED with the information received, have been able to ask all the questions I considered necessary, and all my doubts have been clarified.
Therefore, I GIVE MY CONSENT to undergo lumbar root radiofrequency with epidural catheter.

Patient's Signature: _____ Physician's Signature: _____
Dr. _____

Legal representative's name (if applicable) and relationship (parent, spouse, or guardian):
_____ ID No.: _____

WITHDRAWAL OF INFORMED CONSENT

I revoke my consent for lumbar root radiofrequency with epidural catheter.
Patient's Signature: _____ Date: ____ / ____ / _____