GENERAL INFORMATION

Title: Prospective observational study of the treatment of mechanical low back pain using High-Intensity Focused Ultrasound (HIFU) of the lumbar medial branch.

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Sponsor: Fundació Monclínic

RESEARCH TEAM

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PROTOCOL SUMMARY

Main Objective: To evaluate the clinical efficacy of lumbar medial branch ablation using the HIFU technique at 1, 3 and 6 months.

Primary Variable: Spanish version of the Oswestry Disability Index.

Study Design: Prospective, descriptive, single-center observational study with 6-month follow-up.

Population: Patients with mechanical low back pain without other associated clinical features (neuropathic pain characteristics or strong suspicion of pain originating in other anatomical areas that could cause low back pain) who undergo lumbar medial branch ablation using the HIFU technique.

Total number of participants: Approximately 70–80 patients.

Source of data: Primary source (directly from the patient).

Additional procedures: Baseline assessment and questionnaire; lumbar medial branch ablation with HIFU; telematic follow-up questionnaires at 1, 3 and 6 months.

BACKGROUND AND JUSTIFICATION: Chronic low back pain attributable to degeneration of the facet joints is a prevalent cause of disability, with a significant proportion of cases related to nociceptive conduction through the lumbar medial branch. Radiofrequency ablation (RFA) of the medial branch is the standard minimally invasive treatment for

patients refractory to conservative therapy, although it may be associated with non-negligible local complications. In addition, medial branch RFA requires percutaneous insertion of probes, which may be uncomfortable for the patient and technically demanding.

High-Intensity Focused Ultrasound (HIFU) is an emerging technology that enables non-invasive targeted thermal ablation of deep tissues by concentrating acoustic energy on the target nerve while preserving adjacent structures. Preclinical studies in porcine models have demonstrated that HIFU can denervate the lumbar medial branch with efficacy equal to or greater than RFA without significant adverse effects.

Recent open clinical studies have confirmed the feasibility, safety and effectiveness of HIFU in patients with lumbar facet syndrome, showing response rates similar to RFA and absence of major complications. HIFU offers potential advantages such as non-invasiveness, reduced infection risk and the possibility of repeating the procedure without cumulative damage.

The implementation of HIFU for lumbar medial branch denervation may represent a substantial improvement in the management of chronic low back pain, reducing the aggressiveness of the procedure and minimizing complications. This study protocol aims to collect data on the clinical efficacy of medial branch treatment with HIFU at our center as well as the degree of patient satisfaction.

STUDY HYPOTHESIS: HIFU is an effective, safe and minimally invasive technique for lumbar medial branch ablation in patients with chronic mechanical low back pain.

OBJECTIVES: To evaluate the clinical efficacy of lumbar medial branch ablation using HIFU at 1, 3 and 6 months and to assess patient satisfaction with the therapeutic procedure.

STUDY VARIABLES: A structured questionnaire will record the following variables: patient demographics (age, weight, height), personal medical and surgical history, usual medication, and pain-related data.

Pain variables include the Numeric Verbal Scale (0–10) at rest, during movement and average pain; Spanish version of the Oswestry Disability Index; Spanish version of the Pain Catastrophizing Scale; and the Brief Pain Inventory evaluating the impact of pain on daily activities.

PATIENT FOLLOW-UP: Patients will be evaluated remotely at 1, 3 and 6 months. The following variables will be recorded: pain scores, Oswestry scale, catastrophizing scale,

Brief Pain Inventory, perceived degree of improvement after treatment, changes in pain characteristics, and indication of any new therapeutic approach.

STUDY DESIGN: This is a prospective descriptive observational study conducted at a single center. Recruitment will occur in person at the Pain Unit evaluation visit. Follow-up will last 6 months and will be conducted remotely at 1, 3 and 6 months.

The investigation involves a CE-marked medical device used according to its clinical indication for neuroablation of neural tissue. The system enables targeted thermal ablation of deep tissues in a non-invasive manner by focusing acoustic energy on the target nerve.

PARTICIPANT SELECTION

Recruitment process: Patients attending evaluation or follow-up consultations at the Pain Unit will be sequentially recruited. The study objectives will be explained and patients will sign informed consent if they agree to participate.

Inclusion criteria: Age over 18 years; signed informed consent for data collection; mechanical low back pain with positive diagnostic medial branch block (pain reduction >30%) using local anesthetic.

Exclusion criteria: Age under 18; mixed pain or suspected multiple etiologies (e.g., sacroiliac involvement); active systemic infection; pregnancy; prior spinal surgery at the treatment level; tumors, metastatic disease or osteoporosis in the treatment area; pacemakers or implantable generators; coagulation disorders or thrombocytopenia; vertebral fracture or compression at the treatment level; or health conditions contraindicating sedation or treatment positioning.

STUDY PROCEDURES

Description of the HIFU technique: Pre-procedure fluoroscopy is used to locate the medial branch. The patient is positioned prone with light sedation or local anesthesia. A HIFU transducer focuses acoustic energy on the nerve pathway while avoiding other structures. A single focused exposure lasting approximately 50 seconds with around 1000 joules is delivered, aiming to reach temperatures of 80–85°C to induce thermal necrosis of the nerve.

Post-procedure control: Immediate clinical response and possible adverse effects are evaluated. Follow-up includes pain scales and disability indices.

FOLLOW-UP VISITS: Patients will receive telematic visits at 1, 3 and 6 months after lumbar medial branch ablation with HIFU. These follow-ups are standard practice in Pain Units to evaluate the effectiveness and safety of infiltrative techniques.

STATISTICS

Sample size: Between 70 and 80 patients will be sequentially included.

Statistical analysis: Descriptive statistics will be used. Quantitative variables will be described using mean and standard deviation for normally distributed data, or median and interquartile range for skewed distributions. Qualitative variables will be summarized with absolute frequencies and percentages. Normality will be assessed using Shapiro–Wilk or Kolmogorov–Smirnov tests.

ADVERSE EVENT MANAGEMENT: All suspected adverse events related to the HIFU procedure will be continuously monitored. Events will be recorded with description, date of onset, duration, severity, causal relationship with the procedure and interventions performed.

Events will be classified as mild, moderate or serious adverse events according to regulatory definitions. Serious adverse events will be reported to the study sponsor within 24 hours and to the relevant regulatory authorities and ethics committee according to applicable regulations.

ETHICS AND LEGAL ASPECTS: Data collection will follow the principles of the Declaration of Helsinki, European and Spanish biomedical research regulations, and applicable medical device legislation. Data collection will begin after approval of the protocol by the hospital's Clinical Research Ethics Committee.

Participants will receive information about the study and their participation will be voluntary. They may withdraw at any time without affecting their medical care.

RISK-BENEFIT ASSESSMENT: This observational study does not introduce additional risks beyond those associated with standard HIFU treatment. Potential benefits include improvement of chronic low back pain. Possible risks include temporary discomfort, heat sensation, local redness or rare irritation of nearby nerve structures.

DATA MANAGEMENT: Data will be coded so that patients cannot be directly identified. Only the principal investigators will have access to the coding key and the clinical records.

The database will be stored in a password-protected Excel file on the institution's secure OneDrive. Only authorized investigators will have access.

CONFIDENTIALITY AND DATA PROTECTION: Data processing will comply with the EU General Data Protection Regulation (GDPR) and Spanish data protection legislation. Data will be stored using coded identifiers and may only be accessed by authorized personnel, ethics committees or health authorities when required for verification.

BIOLOGICAL SAMPLES: No biological samples will be collected in this study.

FUNDING: This study does not receive external funding.

DISSEMINATION POLICY: The investigators commit to making the study results public regardless of whether they are positive or negative.