PATIENT INFORMATION FORM

TITLE: "Randomized, single-blind, multicenter, crossover, controlled clinical trial to compare the difference in visual analog scale in two modes of spinal cord stimulation in patients with postlaminectomy syndrome in test phase".
CODE: EST-MED-2018-01.

PROMOTOR: Fundación Instituto de Estudios Ciencias de la Salud de Castilla y León (IECSCYL)-Instituto de Investigación Biomédica de Salamanca (IBSAL)

PRINCIPAL INVESTIGATOR: Dr. ----------
Servicio de Anestesiología, Reanimación y Tratamiento del dolor.

CENTER: Hospital ----------

CONTACT TELEPHONE NUMBER: ----------

INTRODUCTION

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the corresponding Research Ethics Committee in accordance with the current legislation regulating clinical research with medical devices.

Our intention is only that you receive correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To this end, please read this information sheet carefully and we will clarify any doubts that may arise after the explanation. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION

Your participation is completely voluntary. You are free to decide not to participate or to change your decision and withdraw your consent at any time in this study without affecting your current or future medical care.

GENERAL DESCRIPTION OF THE STUDY:

As a participant suffering from post-laminectomy syndrome with leg pain and/or back pain, with insufficient response to medication treatment, you are invited to participate in this study, in which spinal cord stimulation is used to alleviate your pain.

Spinal cord stimulation (spinal cord stimulation) produces analgesia (pain relief) through electrical stimulation by placing one or two electrodes on the spinal column at the dorsal level.

Conventional stimulation causes paresthesias (a kind of tingling), which should cover the entire area of pain. In the present study, a stimulation that does not cause paresthesia (no tingling) will be used.

The study will use the two modes of stimulation, one after the other, starting randomly with one of the two, so that you can compare the response of each of these methods on yourself. Each period will last 5 days, and before and after each stimulation period you will be asked some questions about your pain relief.

The procedure is done under local anesthesia in an operating room under fluoroscopic control. You are placed lying face down. The technique involves inserting one or two wires (electrodes) into your spine. They are placed through a needle, leaving them lodged in the epidural space. To know if the placement site is adequate, you will be asked if you notice a small tingling sensation. A connection will then be made outside the body to attach the electrodes to a temporary battery (external stimulator). This process takes approximately two hours in standard practice. During the study the electrodes will remain connected to the temporary battery (external stimulator). If the result is satisfactory for you, you will be fitted with a definitive device with the type of stimulus that best relieves your pain.

BENEFITS AND RISKS ASSOCIATED WITH THEIR PARTICIPATION IN THE STUDY

This technique, like any medical procedure, has risks. Most of the time the risks do not materialize, and the intervention does not produce undesirable damages or side effects. But sometimes this is not the case. The risks that may appear in this process or intervention during the first days of testing are: 1) You may suffer headaches. It may be severe and require bed rest and treatment with painkillers. It usually disappears in a few days, although sometimes it may last longer. 2) The skin where the electrode comes out may become infected. This may require removal of the electrode. 3) The electrode may move. The stimulation zone may be lost and the electrode may no longer be effective. This would make it necessary to reposition it again in the operating room. Other more serious and exceptional reactions could be: 1) Severe allergic reactions that can cause cardiorespiratory arrest (very rare). 2) Epidural hematoma (blood clot in the area where the electrode is placed). 3) Infection within the nervous system (abscess, meningitis). Severe complications, and quite exceptionally, can lead to death.

Your participation in this study will allow you to know with more precision and accuracy the possibility of having an alternative to conventional methods to improve your chronic pain.

INSURANCE

The study sponsor has an insurance policy that complies with current legislation and that will provide compensation and indemnification in the event of health impairment or injury that may occur in connection with participation in the study.

CONFIDENTIALITY

If you agree to collaborate in this study, you must only allow the collection of the clinical information required for the study. All your data will be handled in the strictest confidence and only your physician will know your identity.

The processing, communication and transfer of personal data of all participating participants will comply with the provisions of Law 15/1999 of 13 December on the protection of personal data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (RGPD). In accordance with the provisions of the aforementioned legislation, you may exercise your rights of access, modification, opposition and cancellation of data, for which you should contact your study doctor.

In addition to the rights you already know (access, modification, opposition and cancellation of data) you can now also limit the processing of data that are incorrect, request a copy or that the data you have provided for the study be transferred to a third party (portability). To exercise your rights, please contact the principal investigator of the study. We remind you that the data cannot be deleted even if you stop participating in the trial in order to ensure the validity of the research and to comply with legal duties and drug authorization requirements. You also have the right to contact the Data Protection Agency if you are not satisfied.

Both the Center and the Sponsor are respectively responsible for the processing of your data and undertake to comply with the data protection regulations in force. The data collected for the study will be identified by a code, so that no information that can identify you is included, and only your study doctor/collaborators will be able to relate such data to you and your medical history. Therefore, your identity will not be disclosed to any other person except to health authorities, when required or in cases of medical emergency. The Research Ethics Committees, the representatives of the Health Inspection Authority and the personnel authorized by the Sponsor will only have access to check the personal data, the procedures of the clinical study and the compliance with the rules of good clinical practice (always maintaining the confidentiality of the information).

The Investigator and the Sponsor are obligated to retain the data collected for the study for at least 25 years after completion of the study. Thereafter, your personal information will only be retained by the Center for your health care and by the Sponsor for other scientific research purposes if you have given your consent to do so, and if permitted by applicable law and ethical requirements.

If we transfer your encrypted data outside the EU to our group entities, service providers or scientific researchers collaborating with us, the participant's data will be protected by safeguards such as contracts or other mechanisms by data protection authorities. If the participant wants to know more about this, he/she can contact the Data Protection Officer of the sponsor.

The data collected for the study will be identified by a code and only your study physician/collaborators will be able to relate this data to you and your medical history.

Only the data collected for the study will be transmitted to third parties and to other countries and will in no case contain information that can directly identify you, such as name and surname, 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 with at least the level of protection of the legislation in force in Spain.

OTHER RELEVANT INFORMATION

Any new information concerning the device used in the study that may affect your willingness to participate in the study, which is discovered during your participation, will be communicated to you by your physician as soon as possible. Your physician agrees to inform you of any relevant new information that becomes known during the study.

If you decide to withdraw consent to participate in this study, no new data will be added to the database and, you may require the destruction of all identifiable samples previously retained to prevent further analysis.

You should also be aware that you may be excluded from the study if the study sponsor or investigators deem it appropriate, either for safety reasons (for any adverse events arising from the device under study) or because they feel that you are not complying with established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

By signing the attached consent form, you agree to comply with the study procedures outlined to you.

Your physician has the right to terminate this study or your individual participation at any time if he/she believes that your continuation in the study could result in significant adverse events.

It is recommended that you keep a copy of this document in your personal file for future reference if desired.

INFORMED CONSENT

STUDY TITLE: "Randomized, single-blind, multicenter, crossover, controlled clinical trial to compare the difference in visual analog scale in two modes of spinal cord stimulation in patients with postlaminectomy syndrome in test phase".

TO BE FILLED IN ONLY BY THE PATIENT (in his/her own handwriting):

I (name and surnames)_____

I have read and understood the information sheet given to me.
I have been able to ask questions about the study and they have been answered.
I have received sufficient information about the study.

I have talken to:_____
(investigator)

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

Whenever I want.
Without having to explain myself.
Without affecting my medical care.

I freely agree to participate in the study.

Date: **Participant Signature**

_____ _____

Date: **Signature of the person explaining the informed consent.**

_____ _____

INFORMED CONSENT - REPRESENTATIVE

STUDY TITLE: "Randomized, single-blind, multicenter, crossover, controlled clinical trial to compare the difference in visual analog scale in two modes of spinal cord stimulation in patients with postlaminectomy syndrome in test phase".

TO BE FILLED IN ONLY BY THE REPRESENTATIVE (in his/her own handwriting):

I (name and surnames)_____
in the capacity of *(relationship with the participant):*
_____
of *(name of the participant) :* _____

I have read and understood the information sheet given to me.
I have been able to ask questions about the study and they have been answered.
I have received sufficient information about the study.

I have talken to:_____
(investigator)

I understand that the participation is voluntary.

I understand that she/he can withdraw from the study:

Whenever he/she wants.
Without having to explain him/herself.
Without affecting the medical care.

In my presence has been given to (name of participant):
_____

all relevant information tailored to his or her level of understanding and agrees to participate.
And I agree that (name of participant)

_____
to participate in this study.

Date: **Representative Signature**

_____ _____

Date: **Signature of the person explaining the informed consent.**

_____ _____

INFORMED CONSENT – WITNESS

STUDY TITLE: "Randomized, single-blind, multicenter, crossover, controlled clinical trial to compare the difference in visual analog scale in two modes of spinal cord stimulation in patients with postlaminectomy syndrome in test phase".

TO BE FILLED IN ONLY BY THE FAIR WITNESS (in his/her own handwriting):

I (name and surnames)_____
declare under my responsibility that: (name of study participant)
_____

Received and understood the information sheet about the study.
You have been able to ask questions about the study and they have been answered.
You have received sufficient information about the study.

Has been informed by _____
(*investigator*)
Understands that participation is voluntary.

You understand that you can withdraw from the study:
1. Whenever he/she wants.
2. Without having to give any explanation.
3. Without any repercussions on your medical care.

And he/she has freely expressed him/her agreement to participate in the study.

Date: **Witness Signature**

_____ _____

ONLY BY THE STUDYPARTICIPANT:

Date: **Participant Signature (footprint or digital signature):**

_____ _____

Date: **Signature of the person explaining the informed consent.**

_____ _____

STUDY TITLE: "Randomized, single-blind, multicenter, crossover, controlled clinical trial to compare the difference in visual analog scale in two modes of spinal cord stimulation in patients with postlaminectomy syndrome in test phase".

REJECTION OF THE INTERVENTION

I (name and surname) _____
(*Name of the PACIENT*)

I do not authorize the performance of this procedure. I assume the consequences for my health or life.

In _____, at _____, 20__

Participant Consent/ Approval of the legal representative

Signed: _____ Signed: _____

WITHDRAWAL OF CONSENT

I (name and surname) _____
(*Name of the PACIENT*)

I have freely and consciously decided to withdraw my consent to this procedure. I assume the consequences for my health or life that may result.

In _____, at _____, 20__

Participant Consent/ Approval of the legal representative

Signed: _____ Signed: _____