PATIENT'S INFORMED CONSENT

Study title:	Efficacy and safety of transcutaneous posterior tibial nerve stimulation in relation to faecal continence in patients undergoing surgery for rectal neoplasia
CEIm Code:	25/080
NCT number:	
Date	29th June 2025
Promotor:	Althaia, Xarxa Assistencial Universitària de Manresa, Fundació Privada
Department:	General and Digestive Surgery
Centre:	Hospital Sant Joan de Déu, Xarxa Assistencial Universitària de Manresa, Althaia

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 Ethics Committee for Research with Medicines of the Institute for Research and Innovation in Life and Health Sciences in Central Catalonia (CEIm IRIS-CC), in accordance with current legislation, the European Regulation on Health Products (EU 2017/745) and Royal Decree 192/2023, of March 21, which regulates health products.

Our intention is that you receive all the correct and sufficient information so that you can decide whether or not to accept to participate in this study. Please take the time you need to carefully read all the information provided below and ask anything you do not understand or that is of particular interest to you. In addition, you can consult with the people you consider appropriate.

Voluntary participation

We invite you to participate in this study because it is believed that the application of new therapies for low anterior resection syndrome is important since it has a functional limitation in patients who suffer from it.

Please note that your participation in this study is voluntary and that you may decide not to participate. If you decide to participate, you may change your decision and withdraw your consent at any time, without this altering your relationship with your doctor or healthcare professionals or causing any harm to your healthcare. If you wish to stop participating in the study, please consult the revocation section.

Objectives

The aim of our study is to evaluate the functional outcomes (incidence of faecal incontinence and sexual dysfunction) of patients post-operatively for rectal neoplasia (tumour) and the application of posterior tibial nerve stimulation (leg nerve) as a therapy to improve anterior resection syndrome (LARS).

Study description

This is a clinical trial study that aims to implement posterior tibial nerve stimulation therapy to demonstrate whether it improves the symptoms of anterior low rectal syndrome (LARS) in patients after rectal neoplasia surgery.

That is, it is a study of two groups (one of them will receive the therapy and the other will not) to demonstrate whether the use of a nerve stimulation device, in this case, stimulating a nerve in the leg (the posterior tibial nerve); can be used to improve the symptoms of anterior low rectal syndrome (LARS) in patients who have undergone rectal tumour surgery.

Anterior low rectal syndrome (LARS) is a problem that can occur after surgery for rectal cancer (especially when the lower part of the rectum has been removed and a direct connection has been made between the colon and the anus).

In simple terms, it is a set of symptoms that affect the way the bowel works after surgery. People who suffer from it may have:

- A strong urge to go to the toilet often (urgency),
- Diarrhoea or very loose stools,
- Difficulty controlling the urge to defecate (incontinence),
- A feeling that the bowel is not emptying properly.

These problems occur because the rectum, which normally serves to store stool before expelling it, is no longer there or does not work properly.

First, you will have answered some questions to determine if you meet the requirements of the study. Once you are included in the study, your participation will consist of carrying out an evaluation of your sphincter function (muscle strength of the anus), quality of life and faecal continence tests, and subsequently carrying out several stimulation sessions with the possibility of being part of the experimental team or the control group. Finally, follow-up visits will be carried out at 6 and 12 months to repeat the quality of life and faecal continence tests in order to evaluate the changes of the application of the therapy.

This study is expected to include 84 patients.

This is not about the administration of any new drugs or medications, but rather the application of neurostimulation to the posterior tibial nerve, stimulation of the nerve that runs through the leg.

The posterior tibial nerve comes from the nerve roots found in the lower spine (S2-S4). This nerve has a mixed function, that is, it controls both movement and sensitivity. Since it comes from the same area as the nerves that control the pelvic floor, it has been observed that if this nerve is gently stimulated (such as through the skin), it can help improve faecal incontinence. This stimulation can activate different nerve pathways in the spinal cord and brain, which helps to improve the pressure of the muscles of the anus and improve the movement and sensitivity of the rectum.

So it has been demonstrated that the use of the neurostimulator at certain parameters goes from having an analgesic effect to stimulating these nerves and being able to improve LARS symptoms such as incontinence in these patients who have had rectal surgery.

The study is designed with two possible treatment groups, half of the group will receive posterior tibial nerve stimulation at therapeutic doses and the other half will receive stimulation at placebo doses to demonstrate the effectiveness of the therapy.

The assignment of each patient to the different study groups will be done randomly.

Neither the doctor/healthcare professionals nor you will know what treatment you will receive. Only the rehabilitator who will provide you with the stimulation device will know which group you belong to, as she will be the one who will program it.

Study activities

Your participation in the study does not imply modifying the treatment you are currently receiving or will receive in the future.

The study will be carried out by two departments. The General Surgery department will be responsible for selecting and introducing patients to the study and will carry out the faecal incontinence and quality of life tests. The activity will take place at the Hospital Sant Joan de Déu. The other department involved is the Physical and Rehabilitation Medicine, which will carry out the patient's sphincter functional assessment (assess the muscle strength of the anus) and explain the process of stimulating the posterior tibial nerve (nerve located in the leg). The activity will take place at the CAP Bages.

Your participation in this study implies that you will have to attend the following visits, apart from the one in the first month post-surgery as is usual for all post-surgery patients, the visit with the pelvic floor doctor and the rehabilitator.

Afterwards there will be 2 follow-up visits with the surgeon (at 6 and 12 months) to repeat the faecal incontinence and quality of life tests to see the evolution. And another visit at 12 months with the rehabilitator to reassess sphincter function.

At the pelvic floor doctor's visit, in order to assess sphincter function, a directed exploration will be performed that will include a rectal examination, an assessment of the strength of the anal sphincter muscles and also a transperianal ultrasound.

6 months after the intervention has been completed (18 months post-IQ), a telephone visit will be made to assess that the patients have not presented any adverse events not recorded during the therapy

	1st month post-surgery	**6th month post-surgery**	**12th month post- surgery**	**18th month post-surgery**
Surgeon visit	X	X	X	

Rehabilitator visit	X		X	
Therapy formation	X			
Collection of demographic and clinical data	X			
Questionnaire administration	X	X	X	
Telephonic visit				X

Risks and discomforts arising from your participation in the study

The device that will be used for the study is marketed and approved as a TENS method for neurostimulation in cases of faecal incontinence, urinary incontinence, to improve pelvic floor strength and also in the context of post-surgical muscle recovery and after sports.

There are many studies that have supported its use, especially in cases of urinary incontinence, but little information is published about its usefulness in cases of faecal incontinence, which is why we are interested in carrying out the following study.

You should know that the healthcare product that is being investigated in the study in which you participate may cause different risks and discomfort or adverse effects. The most frequent and serious could be the following: pain, burning, erythema (redness) pruritus (itching or stinging), allergic reaction to any component of the device. However, you may experience other risks and discomforts that are currently unknown and cannot be ruled out. In all these cases, you should immediately notify your doctor or study healthcare professionals, who should also be informed of any changes in the medication you are taking.

As it is a health product approved by the competent health authorities, there is accessible information in the leaflet about the side effects (TENS manual https://www.manualslib.com/manual/3133728/Med-Fit-3-Plus.html?page=32#manual)

It is also the patient's duty to share responsibilities with the investigator and:

- Comply with the study visits and activities.

- Report any adverse events that occur or changes in medication, warning that, except in case of emergency, do not modify the medication you are taking or take other medications or "medicinal plants" without first consulting with the study doctor or healthcare professionals.

Possible benefits

The use of this technique is intended to improve the faecal continence of patients and, in turn, improve their perceived quality of life. However, there is a possibility that a significant improvement will not appear and therefore that they will not obtain a direct benefit from their participation in the study, either because they find themselves in a situation where the therapy is not effective in their specific case or because they are part of the placebo group. However, all the data obtained from the research could benefit other patients suffering from LARS in the future and contribute to a better understanding and treatment of this pathology.

It is expected that, once the study is completed, if the results are beneficial, they will be offered the possibility of using the neurostimulator in the control group.

Contact in case of doubt

If during your participation you have any questions and/or need more information, you can contact Doctor XXXX of General and Digestive Surgery, via email XXX.

In the event of any doubts regarding neurostimulation therapy, you can contact XXX from CAP Bages ASSIR on XXX telephone.

Expenses and financial compensation

You will not have to pay for the medical product or for the specific tests of the study. Your participation will not entail any additional expenses to your usual clinical practice. Since the costs of the medical product (neurostimulator) will be borne by the general surgery service.

No type of financial compensation is expected during this study, neither for you nor for the research team.

Personal data protection

The sponsor and the research team of the study will guarantee the confidentiality of patient data and will ensure that the provisions of current data protection regulations, both national and European, are complied with at all times.

For more information on confidentiality and protection of personal data, please see Appendix 1.

Why will my data be used?

Your data is necessary for the principal investigator to conduct the study, and will be used as planned in this study, as well as within related research activities with the aim of:

- Better understanding the disease studied and the associated health problems.
- Developing therapeutic methods for your disease.
- Learning from previous studies to plan new studies or improve scientific analysis methods.
- Publish the results of the research in scientific journals or use them for educational purposes.

Right to revoke consent

If you change your mind about participating in the study, you have the right to request to stop participating in this study. In this case, you can contact the principal investigator to inform him (see contact information in the contact section in case of doubt) and no further data will be collected from you and any data already collected will be deleted. However, if your data has already been analysed, we inform you that it will not be possible to delete it.

Acknowledgements

Whatever your decision, the promoter and the research team would like to thank you for your time and attention.

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I, (participant's full name)_____ with ID _____

I have read and understood the information sheet that has been given to me about the study.

I have read Appendix 1 and I agree with its content.

I have been able to ask questions about the study.

I have received sufficient information about the study.

I have spoken with:_____ (researcher name)

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1. Whenever I want.
2. Without having to give an explanation.
    a. Without this fact having an impact on the medical care I receive.

I would like the study doctor/healthcare professional to communicate to me information derived from the research that may be relevant to my health:

☐ Yes, I request to receive this information ☐ No, I do not want to receive this information

Contact telephone or email: _____

I wish the doctor/healthcare professional in the study to communicate to me the information derived from the research (non-genetic) that may be relevant and applicable to my health or that of my family members:

☐ Yes, I request to receive this information ☐ No, I do not want to receive this information

Contact telephone or email: _____

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

I freely give my consent to participate in the study.

Signature:

Participant:	Researcher

Date: _____/_____/_____

(Signature and date to be filled in by the participant).