# STUDY PROTOCOL NCT04964973

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# EFFECT OF TRANSCUTANEOUS ELECTRO-STIMULATION IN AMBULATORY POSTOPERATIVE REHABILITATION TREATMENT IN THORACIC SURGERY.

Servicio
Canario de la Salud

HOSPITAL UNIVERSITARIO DE
GRAN CANARIA DOCTOR NEGRÍN

Gobierno de Canarias

# ANNEX IV

**PATIENT INFORMATION AND INFORMED CONSENT FORM FOR PARTICIPATION IN THE STUDY**

**TITLE: "PAIN CONTROL IN REHABILITATION AFTER THORACIC SURGERY".**

**Principal Investigator: Daniel David Álamo Arce.**

Dear Sir or Madam:

In compliance with Law 41/2002 of 14 November "Basic Law regulating patient autonomy and rights and obligations regarding clinical information and documentation", we reiterate the explanation that your doctor has given you verbally; now in writing, so that you authorise us to include it in the same. It is important that you know and understand the purpose and procedures carried out in this study, read this information carefully and do not hesitate to ask any questions that are not clear to you.

**BACKGROUND**

Inadequate perioperative pain control is the cause of serious medical complications, prolonged hospital stay and unnecessary suffering. For this reason, it is important to apply the best management strategies.

Poor pain control has been shown to increase patient morbidity, as it acts on all systems:

- At the cardiovascular level, severe pain releases catecholamines, which can lead to high blood pressure, arrhythmias and even shock,
- At the respiratory level, it decreases lung function and increases oxygen consumption, as well as decreasing intestinal motility and making urination more difficult.
- It also causes other less serious but equally important disorders such as anxiety, insomnia and hormonal stimulation.

Post-surgical pain creates the following symptoms and signs in patients:

- One of the main fears that patients express before undergoing surgery is the pain that surrounds the entire surgical process.
- Pain associated with injuries imposes activity limitations and thus prevents aggravation of the pathology causing the pain.
- Acute postoperative pain has no useful function and if unrelieved will produce abnormal physiological and psychological reactions that often cause complications.

## AIM

The aim of this study will be to demonstrate four points relating to the activity of physiotherapy. These points will be the following:

1. Physiotherapy techniques are an effective element of pain control in the postoperative chest surgery patient.

2. The quality of life of postoperative chest surgery patients improves with the application of analgesic physiotherapy techniques.

3. Respiratory parameters improve in a shorter time if pain control is carried out during respiratory physiotherapy sessions.

4. The health expenditure involved in caring for these patients decreases considerably.

## DESCRIPTION

This is a prospective, randomized clinical trial study in which the aim is to study the value of an analgesic technique (TENS). The study will be carried out on patients undergoing thoracic surgery for pleural,pulmonary or mediastinal procedures of varying complexity.
Those patients who meet the inclusion criteria will be recruited, depending on the intervention performed.

## INTERVENTION

Their participation in the study is not expected to be detrimental to their health.

One of the fundamental bases of physiotherapy is the intervention in pain control. Post-surgical painin thoracic surgery is considered to be one of the most intense pains that exist. Based on this principle, the aim of this work is to demonstrate that pain control, recovery, readaptation and development of respiratory parameters are normalised with greater precision and in less time.
In relation to the above, your participation in the study could bring you the following benefits as long as you are in the TENS group:

- Better pain control in the process.
- A decrease in the number of days you will need to recover partial and global functionality, both respiratory and functional.
- An improvement in your respiratory function that will prevent or reduce the possibility of acquiring respiratory pathologies such as atelectasis and respiratory infections.

## OBLIGATIONS

Your participation in the study is completely voluntary. You may refuse to participate. You may also withdraw from the study at any time without prejudice or loss of any health benefits to which you are entitled.

You will be informed of any advances or new discoveries made during the duration of this research that may influence your health.

## CONFIDENTIALITY

In accordance with Organic Law 15/1999, of 13 December 1999, on the Protection of Personal Data and the
RD 1720/2007 of 21 December 2007 and other applicable legislation, all data collected during the course of the study will be treated as strictly confidential and will be used solely for the assessment of the study without disclosing your identification data at any time. All persons forming part of the research team are obliged to maintain professional secrecy.

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## ETHICAL COMMITTEES

This study protocol has been brought to the attention of the Ethics and Clinical Research Committee of that hospital.

## DECLARATION

**Mr/Ms:.....with D.N.I. .....**

I HEREBY **GIVE MY AUTHORISATION** to participate in this study.

- I have read the information and have been able to ask questions about it, understanding the purpose and procedures to be carried out in the study.
- I consider that the information I have received is sufficient and I understand it.
- I have spoken to Dr. ..... ( researcher)
- I understand that my participation is voluntary and that I can withdraw from the study at any time without having to explain myself or my medical care.

And for the record, I sign this document, having read and understood it, and of my own free will.

**In Las Palmas de Gran Canaria, at....of.....of.....**

**Signature of Participant**