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A study of how transcutaneous electrical nerve stimulation can be used to decrease pain in patients who have undergone a sternotomy incision

Submission date
29/08/2021

Recruitment status
No longer recruiting

Registration date
11/09/2021

Overall study status
Completed

Last Edited
06/09/2021

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A sternotomy is a type of incision a surgeon does to be able to operate on the heart or other structures under the rib cage. Unfortunately, as with all other surgical incisions, pain is caused and this is mostly due to the cutting of skin, tissues and bone. In many instances, patients may find it difficult to cough, take deep breaths and move their arms due to the pain felt immediately after the surgery. Some patients may also develop pain that lasts for more than 3 months. This type of pain is called Chronic Post-Sternotomy Pain (CPSP) syndrome and it significantly decreases patients' quality of life. There are a variety of pain-relief methods, and most commonly surgeons choose to give patients opioid medication to help decrease the pain. Research shows that this type of pain-relief medication brings about several side effects which may further add to increase the patients' discomfort. Transcutaneous Electrical Nerve Stimulation (TENS) is a safe method for pain relief that uses a small battery-operated device that is attached to the skin by means of sticky pads to provide a mild electrical current. This electrical current may help to decreased pain by reducing the pain signals going to the brain and may also stimulate the body to produce natural pain killers (endorphins). TENS is quite commonly used to treat problems arising from sport injuries, arthritis and labour. However, there is not enough research as to whether TENS, together with opioid medication, is able to decrease pain following a sternotomy incision. Currently in Malta, about 250 patients undergo a sternotomy incision yearly. Physiotherapists treat these patients daily during their stay in hospital, but are not involved in helping to decrease their pain. However, together with the surgeon, anesthesiologist and the rest of the multidisciplinary team, the physiotherapist can have a vital role in managing pain and therefore improving patient satisfaction and hospital costs. The study aims to investigate the effect of TENS, in conjunction with opioid medication, on the pain cause by sternotomy incisions. It also aims to investigate whether TENS helps to improve the patients' functional recovery with regards to lung function and shoulder movements.

Who can participate?
Patients above the age of 18 years who undergo a sternotomy incision

What does the study involve?
Patients who are eligible to participate in the study are identified during a routine assessment before surgery. They are asked to join the study when they are admitted to the hospital the day before the surgery. The participants are then randomly allocated into three groups. Group A will be given a functional TENS unit, group B will be given a placebo TENS unit where the unit appears to be functioning but no electrical stimulation is produced, while group C will serve as the control group and no TENS unit will be given. All three groups will also be receiving the standard care and medication routinely prescribed by the surgeon. In groups A and B, TENS application will start the day after the surgery and will be applied twice a day with each session lasting for 50 minutes. This will be repeated each day until day 4 post-surgery. To be able to assess how well TENS helps to decrease pain, tests concerning pain levels, shoulder movements, lung function and inflammatory markers in the blood will be done at regular intervals during the first 4 days after the surgery. In order to have a baseline, these tests will also be done the day before the surgery when the patient is admitted to the hospital. The tests will also be repeated 3 months after the surgery.

What are the possible benefits and risks of participating?
TENS might help to decrease pain after surgery and help with functional recovery. There may also be benefits to patients undergoing future sternotomies because if the study shows that TENS significantly decreases pain following a sternotomy incision, guidelines may be drawn up on the regular use of TENS following this procedure. There are no known or anticipated risks other than those associated with the surgery as explained by the surgeon.

Where is the study run from?
Mater Dei Hospital (Malta)

When is the study starting and how long is it expected to run for?
October 2020 to March 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Claire Martin
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Transcutaneous electrical nerve stimulation for post-sternotomy pain

Acronym
POSTSTRENPAINTENS

Study objectives
1. There is no significant difference in acute pain in post-sternotomy patients using transcutaneous electrical nerve stimulation versus those that do not.
2. There is no significant difference in forced vital capacity in post-sternotomy patients using transcutaneous electrical nerve stimulation versus those that do not.
3. There is no significant difference in forced expiratory volume in one second in post-sternotomy patients versus those that do not.
4. Transcutaneous electrical nerve stimulation has no effect on shoulder pain in post-sternotomy patients.
5. Transcutaneous electrical nerve stimulation has no effect on shoulder flexion range of motion (ROM) in post-sternotomy patients.
6. Transcutaneous electrical nerve stimulation has no effect on shoulder abduction range of motion in post-sternotomy patients.
7. Transcutaneous electrical nerve stimulation for pain control in acute post-sternotomy patients does not affect chronic post-sternotomy pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 28/04/2021, Faculty of Health Sciences FREC (University of Malta, Faculty of Health Sciences, Room 76, Block A, Level 1, Mater Dei Hospital, Malta; +356 (0)2340 1830; research-ethics.healthsci@um.edu.mt); ref: 8045_13032021_ClaireMartin

Study design
Single-center interventional experimental single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain in post-sternotomy patients

Interventions
Eligible participants will be equally divided into three groups through a computer-generated randomization sequence prepared before the start of the study. The groups will be as follows:
Group A: TENS group – patients receive an application of TENS as an adjunct to opioid and oral analgesia (i.e. standard care)
Group B: placebo TENS group – patients receive an application of placebo TENS as an adjunct to opioid and oral analgesia (i.e. standard care)
Group C: control group – patients receive standard care and no application of TENS.

The study aims to use double-channel, four-electrode TENS units. The four standard sterile disposable electrodes will be placed on the skin on either side of the incision and 2cm away from the suture line. If a dressing is present, this will not be disturbed. The frequency, pulse width and intensity parameters to be used are as follows:
1. Frequency of 80 Hz
2. Pulse Width of at 250 μs
3. Duration of 50 minutes
4. At the strongest intensity that is comfortably tolerable for the patient
Where placebo TENS is to be used, the unit will show an active display, suggesting that the TENS unit is operational, but no electrical stimulation will be produced.

Operational TENS and placebo TENS application will commence on Day 1 post-op (i.e. 24 hours after the sternotomy is done in order to allow for the effects of heavy sedation to wear off and for the patient to be extubated) and will be applied twice daily for 50 minutes duration from Day 1 post-op to Day 4 post-op.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcutaneous Electrical Nerve Stimulator

Primary outcome(s)
1. Pain measured using the Numerical Rating Scale – 11 (NRS-11) at rest and on coughing and during shoulder movements, at baseline (prior to surgery) then twice daily from day 1 – day 4 post-operatively and once after 3 months. In the intervention and placebo groups this will be done twice daily before and after TENS application.
2. Pain-free active shoulder flexion and abduction shoulder movements will be measured using a universal inclinometer at baseline (prior to surgery) then twice daily on days 1 - 4 post-operatively and after 3 months.

Key secondary outcome(s))
1. Pulmonary function data, i.e. Forced Vital Capacity (FVC) and Forced Expiratory Volume in 1 second (FEV 1) will be collected using the Pony FX Spirometer (Cosmed®). All the participants will be tested the day before the surgery and at day 4 post-operatively and after 3 months.
2. CRP testing will be done through blood sample collection on the day before the surgery and from day 1 – day 4 post-operatively

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Patients above the age of 18 years
2. Both male and female patients
3. Elective cardiac surgery via longitudinal median sternotomy
4. Consenting to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous history of chronic pain, drug or alcohol abuse
2. Pre-operative use of narcotics (except for standard protocol pre-operative morphine administered prior to the surgery in question)
3. Pre-operative use of TENS
4. Pre-operative shoulder pain or decrease in shoulder ROM
5. Cancer or metastatic disease
6. Patients with a pacemaker

7. Pregnancy
8. Epilepsy
9. Surgeon reported cognitive impairments
10. Previous sternotomy procedures
11. Other types of incisions different from sternotomies
12. Prolonged mechanical ventilation

Date of first enrolment
12/09/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Malta

Study participating centre
Mater Dei Hospital
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Sponsor information

Organisation
University of Malta

ROR
https://ror.org/03a62bv60

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will be available and all of the individual participant data collected during the trial will be shared after identification. The shared data will be available immediately following the publication date and ending 5 years following article publication.
This data will be shared with researchers who provide a methodologically sound proposal and to achieve the aims in the approved proposal. These proposals should be directed to Claire Martin (claire.martin.04@um.edu.mt). To gain access, data requests will need to sign a data access agreement, and the data will be sent by email.

IPD sharing plan summary
Available on request