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The effect of TENS treatment on pain and mobility after Gamma nail hip fracture surgery

Submission date
05/07/2018

Recruitment status
No longer recruiting

Registration date
30/07/2018

Overall study status
Completed

Last Edited
25/11/2019

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Transcutaneous electrical nerve stimulation (TENS) is a kind of therapy that uses low voltage electrical currents to treat pain. In this study, patients in hospital following surgery for a hip fracture will receive TENS therapy, to see if this results in less pain during the first few days after the surgery compared to patients who received the surgery but not TENS treatment. Additionally, we will be looking at the effects of TENS on mobility and walking.

Who can participate?
Men and women older than 50 years old, with a stable extracapsular intertrochanteric or subtrochanteric hip fracture, that was fixed with a Gamma nail. Patients must have been able to walk for at least ten minutes prior to their hip fracture, and be able to bear weight on the repaired leg.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive active TENS treatment; the other will receive sham TENS treatment (where the TENS device delivers no electric current). Both groups will receive the standard rehabilitation for hip fractures, beginning 24 hours after surgery for the five days they are in hospital. For all participants, electrodes will be taped to the skin on both sides of the surgical cut, through which the TENS treatment will be delivered. Each group will receive active TENS or sham TENS treatment for 30 minutes each day for 5 consecutive days. Active TENS devices will have their intensity adjusted so that the treatment will feel strong, but comfortable. Sham TENS devices will be switched on so that the participant will see a green light, but no current will be delivered.

What are the possible benefits and risks of participating?
The possible benefits are decreased pain after hip fracture surgery, and increased ability to walk and function. There are no known risks to participants taking part in this study.

Where is the study run from?
Galilee Medical Center
89
Nahariya

Israel
22100

When is the study starting and how long is it expected to run for?
The study will start in September 2014 and will run until September 2016.

Who is funding the study?
This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
0110-14-NHR

Study information

Scientific Title
Effects of transcutaneous electrical nerve stimulation on acute postoperative pain intensity, ambulation and mobility after hip fracture: A double-blinded, randomized trial.

Acronym
TENS AND HIP

Study objectives
Incorporating TENS treatment during standard rehabilitation care in the acute post-operative phase following Gamma nail surgical fixation of extracapsular hip fracture will have a beneficial effect in terms of on pain intensity, ambulation and mobility.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki committee of the Galilee Medical Center, 17/11/2014, 0110-14-NHR

Primary study design
Interventional

Study design
Interventional double-blinded single-center randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Extracapsular proximal hip fracture stabilized with Gamma nail

Interventions
Eligible subjects will be randomly allocated to one of two groups (active TENS or sham TENS) using a computer algorithm. Each group will receive the TENS treatment (active or sham) each morning for 5 consecutive days for approximately 30 minutes. Four electrodes will be taped to the skin on both sides of the surgical cut for all participants, and the TENS treatment (active or sham) will be delivered by a portable clinical stimulator TENS device.
Active TENS units will deliver a biphasic symmetric waveform at a continuous frequency of 100 Hz and phase duration of 200 µsec. The participants in this group will be instructed that they should feel a strong but comfortable sensation.
Sham TENS units will be switched on so that the participant will see a green light; however, this device will deliver no current. The participants in this group will be informed that not everyone will necessarily feel stimulation from the device.
Participants in both groups will receive the standard interdisciplinary postoperative treatment, which was 30 minutes of physiotherapy each morning with a physical therapist. Each session involved transfer training, balance exercises, lower extremity exercises and ambulation training.

Intervention Type
Device

Primary outcome(s)
Pain level at rest, at night and during ambulation, measured using a numeric rating scale (NRS) on days 1-5 before participants received TENS and physical therapy (PT) treatment
Ambulation status measured using a functional ambulation classification (FAC) instrument on days 2-5 at the end of the training session, after the participants received TENS and PT treatment
Physical performance tests - sit to stand (repeated five times) and two minute walk, assessed on the final day of treatment (day 5) after participants received TENS and PT treatment

Key secondary outcome(s)
N/A

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Over 50 years of age
2. Stable extracapsular proximal hip fraction (intertrochanteric or subtrochanteric)
3. Partial or full weight bearing instructions
4. Ability to ambulate independently for at least 10 m with or without an assistive device prior to the fracture
5. Ability to follow instructions
6. Mini mental state test score ≥ 20

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
41

Key exclusion criteria
1. Conditions that contraindicate electrical stimulation (i.e. pacemakers, significant sensory loss in lower extremities, local wound at the site of electrode placement)
2. History of cardiovascular, neurological or orthopedic problems with a mobility limitation of walking less than 100 m
3. Prior experience with TENS
4. Infection or systemic disease that may interfere with the rehabilitation process (i.e. lupus disease)

Date of first enrolment
01/12/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Israel

Study participating centre

Galilee Medical Center
89
Nahariya
Nahariya
Israel
22100

Sponsor information

Organisation
Haifa university

ROR
https://ror.org/02f009v59

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2019	25/11/2019	Yes	No