

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of transcutaneous electrical nerve stimulation (TENS) on reduction pain feeling after hip and proximal of femoral fractures surgery

Protocol summary

Study aim

Investigation and study of the effect of TENS on the management and reduction of pain, as well as the amount of distance and duration of starting patients after hip and proximal femur fracture surgery.

Design

A clinical trial with a control group, with parallel groups, double-blind, non-randomized, on 74 patients.

Settings and conduct

The study is carried out in Valiasr Hospital of Arak. Patients are divided into two groups, tennis and control. The patients are evaluated by VAS score in terms of the amount of pain they feel after surgery, and also the amount of walking in the form of partial weight walker and full weight without walker. The study is double-blind, and the researcher and the data analyst are unaware of the allocation of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who, according to the clinical and radiographic findings, suffered a fracture in the pelvis or proximal femur. Exclusion criteria: Patients who do not want to cooperate.

Intervention groups

Four 4 cm² self-adhesive neuromuscular stimulation electrodes were attached to the skin on both sides of the surgical incision of all participants. Active TENS electrical stimulation is performed every morning for 30 minutes for 5 days and a total of 5 treatments. On the first day of treatment, TENS is provided after the physical therapy session. On days 2 to 5, TENS will be applied during ambulatory exercise (10 to 15 minutes) followed by a seated rest period.

Main outcome variables

The level of pain after surgery is evaluated by VAS score within 5 days and then two weeks and three months after surgery. The amount of walking in the form of partial weight is evaluated by examining the amount of walking distance of the patient in a limited period with a walker and full weight is also evaluated as the duration

of walking for 10 meters without a walker.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230103057034N1**

Registration date: **2023-05-02, 1402/02/12**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-02, 1402/02/12**

Update count: **0**

Registration date

2023-05-02, 1402/02/12

Registrant information

Name

Mohammadreza Rasouli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2023-08-20, 1402/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of transcutaneous electrical nerve stimulation (TENS) on reduction pain feeling after hip and proximal of femoral fractures surgery

Public title

Effects of transcutaneous electrical nerve stimulation (TENS) on pain due fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who, according to the clinical and radiographic findings, suffered a fracture in the pelvis or proximal femur.

Exclusion criteria:

Patients who die during surgery or after discharge
Patients who do not want to cooperate

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling will be available. Then, the examined samples in this study are placed in the investigated groups (control and TENS intervention) using random allocation of patients. Two-group randomization on the web (www.graphpad.com) is used to create a simple random sequence. Enter the number of the sample size (74) on the website and the software randomly divided the numbers 1 to 74 into two equal groups A and B, and we considered the numbers A as the TENS group and B as the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is double-blind because the person collecting the information will not be aware of the group of people. The data analyst will not be aware of the group of people

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Arak University of Medical Sciences

Street address

Arak University of Medical Science, Arak

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-03-12, 1400/12/21

Ethics committee reference number

IR.ARAKMU.REC.1400.359

Health conditions studied

1

Description of health condition studied

Osteoporotic hip and femur fractures

ICD-10 code

M80

ICD-10 code description

Osteoporosis with current pathological fracture

Primary outcomes

1

Description

After the surgery, the level of pain is checked with the help of the vas score questionnaire during a 5-day intervention period as explained below: once during the first 24 hours after the surgery, before applying physiotherapy and TENS, and then immediately before each session of physiotherapy and TENS application, by asking the participant, the intensity of pain at night and at rest, the amount of pain experienced the night before and while resting in bed or sitting in a chair during the day is evaluated. In the following, the pain level is assessed once in two weeks after the surgery when the patient visits the orthopedic clinic. Also, the pain level will be measured once with the help of VAS 3 months after the surgery.

Timepoint

once during the first 24 hours after the surgery, before applying physiotherapy and TENS, and then immediately before each session of physiotherapy and TENS application, by asking the participant, the intensity of pain at night and at rest, the amount of pain experienced the night before and while resting in bed or sitting in a chair during the day is evaluated. In the following, the pain level is assessed once in two weeks after the surgery when the patient visits the orthopedic clinic. Also, the pain level will be measured once with the help

of VAS 3 months after the surgery.

Method of measurement

VAS questionnaire to measure the pain level of patients: Visual analog scale (VAS) is a tool that is widely used to measure pain. The patient is asked to indicate their perceived pain intensity (usually) along a 100 mm horizontal line and this rating is then measured from the left edge (= VAS score). VAS score correlates well with acute pain level

Secondary outcomes

1

Description

Partial weight walking

Timepoint

Before discharge

Method of measurement

The amount of distance traveled in two minutes

2

Description

Full weight walkinf

Timepoint

After discharg

Method of measurement

The time required to reach the full weight setup of 10 steps

Intervention groups

1

Description

Intervention group: In the intervention group, after receiving the standard post-surgery treatment, physiotherapy with a device with a frequency of 180-250 volts is performed every morning for 30 minutes by a physiotherapist, depending on the patient's tolerance. Each treatment session includes transfer training, balance exercises, lower limb exercises and ambulatory exercises that are performed at the end of the session. Before walking, four self-adhesive neuromuscular stimulation electrodes measuring 4 square centimeters are attached to the patient's skin on both sides of the surgical incision. Electrical stimulation (TENS) is performed every morning for 30 minutes for 5 days. On the first day, TENS treatment is provided after the physiotherapy session. On days 2 to 5, TENS is applied during ambulatory exercise (10 to 15 minutes) and a seated rest period afterward.

Category

Treatment - Other

2

Description

Control group: patients in the control group only receive the standard treatment of postoperative patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Mohammad Reza Rasouli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammadreza Rasouli

Position

Student

Latest degree

A Level or less

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available