Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Trans cutaneous Electrical Nerve Stimulation (TENS) on health-related quality of life , Harris hip score and mortality rate in patients after surgical treatment of osteoporotic hip and pre-trochanteric fractures

Protocol summary

Study aim

Effect of Trans cutaneous Electrical Nerve Stimulation (TENS) on health-related quality of life, Harris hip score and mortality rate in patients after surgical treatment of osteoporotic hip and pre-trochanteric fractures

Design

A clinical trial with a control group, with parallel groups, double-blind, non-randomized, on 370 patients.

Settings and conduct

The aim of this study is to investigate the effect of Transcutaneous Electrical Nerve Stimulation (TENS) on quality of life, hip function, and mortality in patients after hip and proximal femur osteoporotic fracture surgery on 370 hip and hip fracture surgery patients on Valiasr Hospital. The patients were divided into two intervention groups, control group and random group. All patients received common post-operative supportive treatment after the operation, and the intervention group underwent physiotherapy and TENS for five days. The information of the patients and the criteria required for the study will be analyzed by a questionnaire in months 1, 3, 6, and 12. 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: 1. Osteoporotic hip or proximal femur surgery patients 2. Patients over 50 years old exclusion criteria: Unwillingness of patients to cooperate

Intervention groups

Intervention group: TENS is applied for 5 days after the operation. Control group: patients receive standard treatment after surgery without TENS.

Main outcome variables

Quality of Life; Hip function; Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056365N1**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name

Mohammad reza Bozorgmanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-29, 1401/01/09

Expected recruitment end date

2024-03-28, 1403/01/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Trans cutaneous Electrical Nerve Stimulation (TENS) on health-related quality of life , Harris hip score and mortality rate in patients after surgical treatment of osteoporotic hip and pre-trochanteric fractures

Public title
Effect of Trans cutaneous Electrical Nerve Stimulation(TENS) on fractures

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Osteoporotic hip and pre-trochanteric fractures patients
Over 50 years patients
Exclusion criteria:
Patients with unwillingness to cooperate

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **370**

Randomization (investigator's opinion)
Randomized

Randomization description
Non-random sampling will be available. Then, the examined samples in this study will be placed in the investigated groups (control and TENS intervention) random allocation sequence was done using Random Allocation software. In the software, enter the sample size number (370) and the software randomly divided the numbers from 1 to 370 into two equal groups, A and B, and we considered the numbers A as the control group and B as the TENS group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is double-blind because the participants who receive the intervention are aware of the intervention. 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 Univercity of Medical Science, Arak
City
Arak
Province
Markazi
Postal code
3848176341

Approval date
2022-04-02, 1401/01/13

Ethics committee reference number
IR.ARAKMU.REC.1401.005

Health conditions studied

1

Description of health condition studied
Osteoporotic hip and femur fractures

ICD-10 code
M16

ICD-10 code description
Osteoarthritis of hip

Primary outcomes

1

Description
Quality of life

Timepoint
1, 3, 6 , 12 month after surgery

Method of measurement
SF36 questionnaire

2

Description
Hip function

Timepoint
1, 3, 6 and 12 month after surgery

Method of measurement
Harris hip score

3

Description
Mortality

Timepoint
Immediately and 1, 3 , 6 , 12 month after surgery

Method of measurement
Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after receiving the standard post-surgery treatment, physiotherapy is performed by the physiotherapist every morning for 30 minutes with a device with a frequency of 180-250 volts, 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
Taraneh Rezaei
Street address
Valiasr hospital ,Valiasr square, Arak
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mehdi Salehi
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3848176341
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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
Mohammad Reza Bozorgmanesh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Reza Bozorgmanesh

Position
Assistant professor

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Person responsible for updating data

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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