Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Comparison of the effect of exercise therapy with electroacupuncture with exercise therapy with electrical percutaneous nerve motility on pain, physical function and gait in people with complete hip arthroplasty

Protocol summary

Study aim
Comparison of the effect of exercise therapy with electroacupuncture with electrical stimulation of percutaneous nerve along with exercise therapy on pain, physical function and walking speed in people with complete hip arthroplasty.

Design
Clinical trial with control group, with parallel groups, double-blind, non-randomized, on 20 patients. 1 phase

Settings and conduct
At home, electroacupuncture and TENS interventions and exercise therapy will be performed. Participant, therapist and blind evaluator. The participant is aware of the inclusion in the study and fills out the satisfaction form. The therapist only knows what he is going to do. The evaluator also has no knowledge of the study groups.

Participants/Inclusion and exclusion criteria
People who have had hip arthroplasty and are over 60 years old and also do not have any specific infections and do not have an underlying disease who is taking pain medication.

Intervention groups
Electroacupuncture with regular exercise therapy for one group and TENS intervention with exercise therapy for the other group

Main outcome variables
Reduce pain, reduce edema, increase physical function and gait in people with hip arthroplasty

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191208045652N4**
Registration date: **2021-11-04, 1400/08/13**
Registration timing: **prospective**
Last update: **2021-11-04, 1400/08/13**
Update count: **0**

Registration date
2021-11-04, 1400/08/13

Registrant information

Name
marzieh Yassin

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-21, 1400/09/30

Expected recruitment end date
2022-06-20, 1401/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of exercise therapy with electroacupuncture with exercise therapy with electrical percutaneous nerve motility on pain, physical function and gait in people with complete hip arthroplasty

Public title
The effect of electroacupuncture and exercise therapy on pelvic surgery

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing hip arthroplasty surgery one to two days after surgery People aged 60 and over The surgical incision is anterior-external and the head of the hip bone and acetabulum have been replaced Patients' pain at the time of initial evaluation after surgery should be at least 3 cm based on a numerical pain rating scale Ability to read and write in cycles Ability to walk at least 50 meters History of neurological diseases that cause patients to be unable to function
Exclusion criteria:
Re-hip surgery Existence of infection after hip replacement surgery Partial loss of hip or acetabulum during study due to interventions History of using painkillers that are outside the treatment regimen of a specialist physician while studying or are different from other painkillers used by other patients Patients with diabetes, etc. who use painkillers to reduce joint pain
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, the therapist, and the person evaluating the participants go blind. Of course, participants are given enough information about how to enter the study first and they are explained. For physiotherapist, which also uses electroacupuncture or exercise therapy, it is blinded to prevent bias for interventions. Outcome assessment is also done for the person who does not know which group the participant is in and wants to score based on guesswork.
Placebo
Used
Assignment
Parallel
Other design features
In this study, for the first time, electroacupuncture for people who have had hip arthroplasty is examined to measure its effects.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences
Street address
Sattar Khan Street. Nyayesh Street. Rasoul Akram Hospital.
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Tehran
Province
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۱۴۴۹۶۱۴۵۳۵
Approval date
2021-10-16, 1400/07/24
Ethics committee reference number
IR.IUMS.REC.1400.638

Health conditions studied

1

Description of health condition studied
Total Hip Arthroplasty (THA)
ICD-10 code
M16
ICD-10 code description
Osteoarthritis of hip

Primary outcomes

1

Description
In this study, the amount of pain is the primary outcome variable because the sample size and inclusion criteria are determined based on this variable.
Timepoint
Days 1, 5, 15 and 30 of the intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Physical function
Timepoint
Days 1, 5, 15 and 30 of the intervention
Method of measurement
Hip Disability and Osteoarthritis Outcome Score (HOOS), Three tests of maximum walking speed, 3-minute walking test and sitting and standing up test

2

Description
edema of the entire lower limb
Timepoint
Days 1, 5, 15 and 30 of the intervention
Method of measurement
Using a tape measure, the edema of the entire lower limb is measured in areas 10 cm above the knee joint, the middle part of the leg as well as the middle area of the foot.

3

Description
Hip Range of motion
Timepoint
Days 1, 5, 15 and 30 of the intervention
Method of measurement
A goniometer is used to measure the range of motion of the hip joint.

Intervention groups

1

Description
Intervention group: the intervention group, the first session of treatment will use electroacupuncture along with exercise therapy.DZ-II NERVE AND MUSCLE STIMILATOR made in China in 2016 will be used.Sterile disposable needles with a diameter of 0.25 mm and a length of 50 mm will be used by the SMS company South Korea, produced in 2019. Electroacupuncture device settings include 2 Hz frequency, conventional mode, duration 20 minutes. The needles are attached to the device and attach to 10 points on the body.
Category
Treatment - Other

2

Description
Control group: In the control group, the first session will use TENS. In this group, 10 sessions of exercise therapy with electrical stimulation through the skin with the help of the SDZ-II NERVE AND MUSCLE STIMILATOR device Made in China, it is used in the area of pain. While the supine patient is lying on the bed, the 4 electrodes of the device are closed diagonally in the patient's pain range, electrical stimulation with a frequency of 100 Hz is applied for 20 minutes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid hospital
Full name of responsible person
Marzia Yassin
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Marzia Yassin

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
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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
Not applicable

Data Dictionary
Not applicable