

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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)

Phone

+98 21 2222 8052

Email address

m.yassin.pt@gmail.com

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.

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

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 STIMULATOR 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 STIMULATOR 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

Street address

Hemmat Gharb Highway, after Sattari Highway, south of Shahid Kabiri Tameh St. (North Shahin), Bahar St., No. 15, floor

City

Tehran

Province

Tehran

Postal code

2144491602

Phone

+98 21 4448 0185

Fax

+98 21 4449 2187

Email

info@hospitalomid.com

Web page address

<https://omid.hospital/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, 5-th floor of the headquarters

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 8670 5503

Email

Research-m@iums.ac.ir

Web page address

<https://vcr.iums.ac.ir/>

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

+98 21 2222 8052

Person responsible for general inquiries

Fax

+98 21 8862 2703

Email

m.yassin.pt@gmail.com

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

Physiotherapy

Street address

Sattar Khan Street. Nyayesh Street. Rasoul Akram Hospital, Physiotherapy department

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 2222 8052

Email

m.yassin.pt@gmail.com

Person responsible for updating data

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

Physiotherapy

Street address

Sattar Khan Street. Prayer Street. Rasool Akram Hospital. Physiotherapy department

City

Tehran

Province

Tehran

Postal code

۴۴۹۶۱۴۵۳۵

Phone

+98 21 2222 8052

Email

yassin.m@iums.ac.ir

Person responsible for scientific 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

Physiotherapy

Street address

Sattar Khan Street. Nyayesh Street. Rasoul Akram Hospital, Physiotherapy department

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

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