

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Effect of 6 weeks of Combined Rehabilitation Program (electrical stimulation and isometric contraction) on pain and function in athletes with knee osteoarthritis

Protocol summary

Study aim

The Effect of 6 weeks of Combined Rehabilitation Program (electrical stimulation and isometric contraction) on pain and function in athletes with knee osteoarthritis

Design

The clinical trial consisted of three experimental group and a control group, with parallel and random groups. The Random allocation software was used for randomization

Settings and conduct

The present study is a quasi-experimental research with a pretest-posttest design with three experimental groups and one control group. 32 Athletes with Knee Osteoarthritis are randomly divided into four test and control groups. Pain and performance variables are measured before and after exercise.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having mild to moderate primary osteoarthritis, male gender, not having any arthroscopic surgery; Exclusion criteria: taking painkillers and anti-inflammatory drugs, participating in any exercise program at least six months before the research

Intervention groups

The first intervention group includes athletes with knee osteoarthritis who receive electrical stimulation intervention. The second intervention group includes athletes with knee osteoarthritis who receive isometric contraction intervention. The third intervention group includes athletes with osteoarthritis of the knee who receive the intervention of electrical stimulation and isometric contraction. The control group includes athletes with osteoarthritis of the knee who do not receive the intervention.

Main outcome variables

Pain and Performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200107046035N10**

Registration date: **2022-06-28, 1401/04/07**

Registration timing: **prospective**

Last update: **2022-06-28, 1401/04/07**

Update count: **0**

Registration date

2022-06-28, 1401/04/07

Registrant information

Name

Hossein Shahrokhi

Name of organization / entity

Hakim Sabzevari University

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 2756

Email address

h.shahrokhi@hsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 6 weeks of Combined Rehabilitation Program (electrical stimulation and isometric contraction) on pain and function in athletes with knee osteoarthritis

Public title

The Effect of Combined Rehabilitation Program on pain and function in athletes with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to moderate primary osteoarthritis Male Gender Do not have any arthroscopic surgery Lack of musculoskeletal disease in other parts of the body

Exclusion criteria:

Taking painkillers and inflammation Arthritis Participate in any exercise program at least six months prior to research

Age

From **45 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple Randomization Method was used to assign individuals to 4 groups that in this method, Random Allocation Software was used to create a random sequence. Then, in order not to determine which group the individuals will be assigned to before dividing them into two groups, or in other words, allocation concealment, the central randomization method was used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport sciences research institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.SSRC.REC.1401.010

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

At the beginning of the study (before the start of the intervention) and after 6 weeks of intervention

Method of measurement

Visual Analogue Scale

2

Description

Function

Timepoint

At the beginning of the study (before the start of the intervention) and after 6 weeks of intervention

Method of measurement

6-min walk test and Stair climb and descent and 40m (4x10m) Fast Paced Walk Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Electrical stimulation, for 6 weeks, 3 sessions per week, 2 hour per session

Category

Treatment - Other

2

Description

Intervention group: Isometric contraction, for 6 weeks, 3 sessions per week, 2 hour per session

Category

Treatment - Other

3

Description

Intervention group: Electrical stimulation and Isometric contraction, for 6 weeks, 3 sessions per week, 2 hour per session

Category

Treatment - Other

4

Description

Control group: Without any training and just doing normal daily activities

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafagh University

Full name of responsible person

Seyed Arman Nikoo

Street address

20th Mordab Ave, Nashtaroud

City

Tonekabon

Province

Qazvin

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4683165363

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+98 11 5426 6957

Email

eli1400140014001400@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shafagh University

Full name of responsible person

Mohammad Fallahmohamadi

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20th Mordab Ave

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Mazandaran

Postal code

4683165363

Phone

+98 11 5426 6957

Email

info@shafagh.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shafagh University

Proportion provided by this source

10

Public or private sector

Private

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

Hakim Sabzevari University

Full name of responsible person

Hossein Shahrokhi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Corrective Exercise

Street address

Tohid Shahr - Sabzevar - Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period one year after printing the results

To whom data/document is available

Data will be available to academic and scientific researchers

Under which criteria data/document could be used

Any kind of functional analysis on the submitted data is allowed

From where data/document is obtainable

by Email: h.shahrokhi@hsu.ac.ir

What processes are involved for a request to access data/document

by Email: h.shahrokhi@hsu.ac.ir and the reason for using the documents

Comments

Person responsible for updating data

Contact

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

Hossein Shahrokhi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Corrective Exercise

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