

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effects of therapeutic ultrasound on postural sway indices in women with knee osteoarthritis

Protocol summary

Study aim

Effects of the pulsed ultrasound on postural sway indices in women with knee osteoarthritis

Design

Randomized clinical trial, no blinding Patients with knee osteoarthritis were randomly assigned to one of the three intervention groups by using sealed envelope

Settings and conduct

After initial evaluation and check the conditions of the inclusion and exclusion criteria by rheumatologist, patients were referred to Tarbiat Modares University for evaluation and interventional therapy. The venue of the research was in No. 2 Faculty of Medicine, Tarbiat Modares University, Tehran.

Participants/Inclusion and exclusion criteria

Primary symptomatic knee osteoarthritis for at least 6 months Not having any contraindications for treatment with ultrasound (like cancer, wound, ...) Should not present neuromuscular, musculoskeletal, chronic inflammatory disorders, diabetes or any other conditions that could affect the balance of the patients Not having osteoporosis

Intervention groups

1) Placebo ultrasound plus exercise therapy group: 10 sessions of sham ultrasound with isotonic and isometric exercises of the lower limbs 2) Ultrasound group: 10 sessions of treatment with pulsed ultrasound 3) Ultrasound plus exercise therapy group: 10 sessions of treatment with pulsed ultrasound with performing isotonic and isometric exercises of the lower extremities 4) Healthy subjects group: Just make initial evaluations for comparison with patient groups

Main outcome variables

Center of Pressure Path Length Center of Pressure displacement range Center of Pressure displacement velocity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161015030306N2**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

seyed mehdi mohsenipour

Name of organization / entity

tarbiat modares university

Country

Iran (Islamic Republic of)

Phone

+98 82880021

Email address

m.mohsenipour@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

tarbiat modares university

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2016-04-03, 1395/01/15

Actual recruitment end date

2016-09-22, 1395/07/01

Trial completion date

empty

Scientific title

Effects of therapeutic ultrasound on postural sway indices in women with knee osteoarthritis

Public title

Effects of therapeutic pulsed ultrasound on balance in women with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primary symptomatic knee osteoarthritis for at least 6 months Women between the ages of 40 and 73 years No other treatments for 6 months prior to the study

Exclusion criteria:

No contraindications for treatment with ultrasound (like cancer, wound, ...) Subjects should not present serious neurologic and systemic diseases, musculoskeletal or chronic inflammatory disorders, diabetes or any other conditions that could influence the balance of the patients Not having osteoporosis

Age

From **40 years** old to **73 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

N/A

Randomization description

Randomization with sealed envelopes. subjects pick up one envelope and enter one of the three groups of intervention by chance.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr, Jalal e al e ahmad, Tehran

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR.TMU.REC.1394.249

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M15-M19

ICD-10 code description

In this block the term osteoarthritis is used as a synonym for arthrosis or osteoarthrosis. The term primary has been used with its customary clinical meaning of no underlying or determining condition identified.

Primary outcomes

1

Description

Center of Pressure path length, Center of Pressure displacement Range, Center of Pressure displacement velocity

Timepoint

Before intervention, 2 till 4 days after intervention

Method of measurement

Force plate

Secondary outcomes

1

Description

Pain, functional balance status

Timepoint

Before intervention. 2 till 4 days after intervention

Method of measurement

Visual Analogue Scale questionnaire, WOMAC questionnaire, Lequesne questionnaire, Timed Up and Go Test, 6 Minute Walk Test

Intervention groups

1

Description

Placebo ultrasound plus exercise therapy group: Advise plus off ultrasound plus exercise therapy. Ultrasound group: Advise plus pulsed ultrasound. Ultrasound plus exercise therapy group: Advise plus pulsed ultrasound plus exercise therapy. Healthy subjects group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatallh hospital

Full name of responsible person

Dr Nooshin Bayat, Rheumatologist, Professor of
Baqiatallah University

Street address

Sheikh bahaei st, Mollasadra st, Vanak square

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۹۱۵۳۷۱

Phone

+98 21 8805 0436

Email

Nobayat@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Vice head of research

Street address

No. 3 Faculty of Medicine, Tarbiat Modares University,
Jalal e Al e Ahmad, Tehran.

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 2009

Fax

+98 21 8800 6544

Email

Res@modares.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tarbiat Modares University

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**

Tarbiat Modares University

Full name of responsible person

Roya Ravanbod

Position

Ph.D of Physical Therapy, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

No 3 Faculty of medicine, Tarbiat Modares University,
Jalal e Al e Ahmad

City

Tehran

Province

Tehran

Postal code

14115-111

Phone

+98 21 8288 3287

Fax**Email**

rravanbod@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Seyed Mehdi Mohsenipour

Position

Msc student of physical therapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No. 3 Faculty of medicine, Tarbiat Modarwes
University, Jalal e Al e Ahmad

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3287

Fax**Email**

mohsenipour@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Roya Ravanbod

Position

Ph.D of physical therapy, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

No. 3 Faculty of medicine, Tarbiat Modares University,
Jalal e Al e Ahmad

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3287

Fax

Email

rravanbod@hotmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

If the data would be necessary for a research, only after evaluation and permission from the vice head of research of Tarbiat Modares university

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data of the study includes postural sway indices, changes in pain and functional status. The data of major outcome is shareable and personal informations are not shareable.

When the data will become available and for how long

Access after the thesis defence

To whom data/document is available

Physiotherapy colleagues and other researchers

Under which criteria data/document could be used

For research and treatment purposes

From where data/document is obtainable

1) Seyed Mehdi Mohsenipour with electronic mail: Mohsenipour@hotmail.com 2) Roya Ravanbod with electronic mail: rravanbod@modares.ac.ir

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

The applicant can access the data in one week by sending email to any of top electronic mails.

Comments