

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effects of Isometric exercise of vastus medialis oblique Muscle; with and without electromyographic biofeedback on voluntary muscle activity, maximal muscle thickness, pain and function in patients with knee osteoarthritis

Protocol summary

Summary

This study is designed to compare the effect of isometric exercise of vastus medialis oblique muscle with and without electromyographic biofeedback in voluntary muscular activity, maximal muscle thickness, clinical symptoms and activity of daily living (ADL) in patients with knee osteoarthritis. Knee osteoarthritis is the most common joint disease, but despite a variety of non-surgical procedures, so far there is no general consensus on the priority of treatment. This study is a single-blind randomized controlled clinical trial on 41 patients with mild to moderate osteoarthritis who come to Shahid Moddares Hospital. Patients with pain or joint swelling and radiologic findings of joint destruction since 6 months ago based on knee osteoarthritis criteria of The ACR (grade 2, 1 of Kellgren-Lawrence scale) will be recruited. Exclusion criteria are patients under treatment of corticosteroid usage and etc. In one group 12 sessions isometric exercise of vastus medialis oblique muscle with biofeedback, and 12 sessions exercise without feedback in other group will be done. Voluntary muscular activity with biofeedback device, maximal muscle thickness with ultrasonography, Pain, function, maximum distance walking and ADL will be measured through WOMAC and Lequesne questionnaires before and 2 months after exercise in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041513442N14**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Isometric exercise of vastus medialis oblique Muscle; with and without electromyographic biofeedback on voluntary muscle activity, maximal muscle thickness, pain and function in patients with knee

osteoarthritis

Public title

Effect of Biofeedback on Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: arthralgia since the past 6 months; radiologic evidence of articular damage (grade 2,1 of Kellgren-Lawrence scale) based on knee OA criteria of ACR. Exclusion criteria: systemic diseases such as diabetes mellitus and collagen vascular disorders; history or presence of cancer or malignant disorders; any infection and active wound of the knee; presence of immunosuppressive, autoimmune disorders; recent history of severe trauma to the knee; age less than 45 or over 70 year; genu valgum/varum greater than 20 degrees.

Age

From **51 years** old to **26 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committe Of, Shahid Beheshti University Of
Medical Siences

Street address

Ethic Committe Of Shahid Beheshti University Of
Medical Siences, Velenjak, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-10-23, 1395/08/02

Ethics committee reference number

IR.SBMU.MSP.REC.1395.344

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis (Gonarthrosis)

ICD-10 code

M17.0

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

pain

Timepoint

at the beginning and after 2 months

Method of measurement

womac, Lequesne questionnaire

2

Description

joint stiffness

Timepoint

at the beginning and after 2 months

Method of measurement

womac questionnaire

3

Description

functional limitation

Timepoint

at the beginning and after 2 months

Method of measurement

womac questionnaire

4

Description

walking ability

Timepoint

at the beginning and after 2 months

Method of measurement

Lequesne questionnaire

5

Description

activities of daily living

Timepoint

at the beginning and after 2 months

Method of measurement

Lequesne questionnaire

6

Description

Voluntary muscular activity

Timepoint

at the beginning and after 2 months

Method of measurement

biofeedback device

7**Description**

maximal muscle thickness

Timepoint

at the beginning and after 2 months

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: 12 sessions isometric exercise of vastus medialis oblique muscle with electromyographic biofeedback

Category

Rehabilitation

2**Description**

Intervention group 2: 12 sessions isometric exercise of vastus medialis oblique without feedback

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Modarres Hospital

Full name of responsible person

Zeynab Bossaghzade

Street address

Shahid Modarres Hospital, Kaj Square, Saadat Abad Street, Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

Street address

Physical Medicine and Rehabilitation Department, Shahid Modarres Hospital, Kaj Square, Saadat Abad, Tehran

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Tehran

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

Yes

Title of funding source

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zeynab Bossaghzade

Position

Resident in Physical Medicine and Rehabilitation

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty