Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
+98 21 2273 1112
Email address
a_raeissadat@sbmu.ac.ir

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

City

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 Univeraity of Medical Sciences

Full name of responsible person

Zeynab Bossaghzade

Position

Resident in Physical Medicine and Rehabilitation

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 2273 1112

Fax

Email

zeynabbossaghzade@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate Professor

Other areas of specialty/work

Street address

Shahid Modarres Hospital, Kaj Square, Saadat Abad

Street, Tahran
City
Tehran
Postal code
Phone
+98 21 2207 4090
Fax
Email
a_raeissadat@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti Univeraity of Medical Sciences
Full name of responsible person
Zeynab Bossaghzade
Position
Resident in Physical Medicine and Rehabilitation
Other areas of specialty/work
Street address
Shahid Modarres Hospital, Kaj square, Saadat Abad street, Tehran
City
Tehran
Postal code
Phone
+98 21 2207 4090
Fax
Email
zeynabbossaghzade@yahoo.com
Web page address

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