

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of leg muscles exercise on clinical improvement of knee osteoarthritis

#### Protocol summary

Tabriz University of medical sciences

#### Summary

Adding calf muscles physical therapy to the ordinary physiotherapy, can improve functional state of patients with knee osteoarthritis. Sixty patients are set in two intervention and control groups randomly. In intervention group we will add calf muscles strengthening and stretching exercises on knee physiotherapy during 20 sessions. Before and after program, functional tests as WOMAC, Lequesne questionnaire and falling risk with balance system would be tested to compare groups.

#### Expected recruitment start date

2009-11-22, 1388/09/01

#### Expected recruitment end date

2010-01-21, 1388/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Scientific title

Effect of leg muscles exercise on clinical improvement of knee osteoarthritis

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT138808132664N1**

Registration date: **2009-12-18, 1388/09/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2009-12-18, 1388/09/27

#### Public title

Effect of leg muscles exercise on clinical improvement of knee osteoarthritis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: moderate knee osteoarthritis Exclusion criteria: severe systemic illness, joint injection, surgery or physical therapy within last six months

#### Age

From **40 years** old to **80 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Registrant information

#### Name

Yaghoub Salekzamani

#### Name of organization / entity

Tabriz University of medical sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 41 1337 3967

#### Email address

salekzamani@tbzmed.ac.ir

#### Recruitment status

Recruitment complete

#### Funding source

## Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of medical sciences

##### Street address

Imam Reza Hospital

##### City

Tabriz

##### Postal code

##### Approval date

2009-04-01, 1388/01/12

##### Ethics committee reference number

173/4/5

## Health conditions studied

### 1

#### Description of health condition studied

knee osteoarthritis

#### ICD-10 code

M19

#### ICD-10 code description

Other arthrosis

## Primary outcomes

### 1

#### Description

Functional improvment

#### Timepoint

Before and after 20 sessions of physiotherapy

#### Method of measurement

WOMAC & Lequesne Questionnaires

## Secondary outcomes

### 1

#### Description

Falling Risk

#### Timepoint

Before and after 20 sessions of physiotherapy

#### Method of measurement

Biodex Balance system

## Intervention groups

### 1

#### Description

Control group: only routine physiotherapy

#### Category

Rehabilitation

### 2

#### Description

Intervention group: routine physiotherapy and calf muscles strengthening and stretching excercises

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Imam Reza Hospital

##### Full name of responsible person

Yaghoub Salekzamani

##### Street address

Golgasht st.

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research vice-chancellor of Tabriz univercity of medical sciences

##### Full name of responsible person

Mir Ali Eteraf Oskouee

##### Street address

Tabriz univercity of medical sciences

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research vice-chancellor of Tabriz univercity 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*

+98 41 1337 3967

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**Email**

salekzamaniy@tbzmed.ac.ir

**Web page address**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz university of medical sciences

**Full name of responsible person**

Yaghoub Salekzamani

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz univercity of medical sciences

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Babak Kolahi

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Resident

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## Person responsible for scientific inquiries

### Contact

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**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Golgasht st.

**City**

Tabriz

**Postal code**

**Phone**

## 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*