

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison the effects of acupuncture, physical modality and home based exercise training on symptoms of knee osteoarthritis

#### Protocol summary

##### Summary

Aim: to compare the effects of acupuncture, physical modality and home based exercise training on symptoms of knee osteoarthritis. Patients: all patients with knee osteoarthritis, according to American college of rheumatology (ACR) criteria, referred to the clinic of physical therapy in Firoozgar hospital, Tehran, Iran. Main inclusion criteria were knee pain lasting for 6 months or longer and age between 40-65 years. Main exclusion criteria were receiving NSAIDs during study and exacerbation of symptoms. Sixty patients with knee osteoarthritis were randomly divided into three groups (A,B and C). The acupuncture group (A) received only acupuncture at selected acupoint for knee pain; the physical modality group (B) received TENS (transcutaneous Electrical Nerve Stimulation), ultrasound and hot pack at pain areas. The exercise group (C) received isometric exercise of the knee. Each group received treatment 3 sessions per week for 4 weeks. Evaluating measurement tools were Visual Analogue Scale (VAS) for pain intensity and KOOS questionnaire for function.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138811163284N1**

Registration date: **2009-04-21, 1388/02/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-04-21, 1388/02/01

##### Registrant information

###### Name

Dr Bijan Forogh

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8214 1229

##### Email address

bijhanfr@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Iran university of medical sciences

##### Expected recruitment start date

2009-04-21, 1388/02/01

##### Expected recruitment end date

2009-11-30, 1388/09/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effects of acupuncture, physical modality and home based exercise training on symptoms of knee osteoarthritis

##### Public title

Effects of acupuncture, physiotherapy and exercise training on knee arthrosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1-Male and female with knee pain lasting for 6 months or longer 2-Age between 40-65 years 3-Normal neurological examination 4-At least one osteophyte at tibiofemoral joint (Kellgren- Lawrence

grade >2) 5-Not receiving intra articular injection from 3 months ago 6- Not consuming NSAIDs during last week before study 7-No history of knee surgery 8-No history of treatment with acupuncture 9-No history of cancer, pregnancy and secondary osteoarthritis. Exclusion criteria: 1-Low adherence to treatment 2-Receiving NSAIDs during study 3-Exacerbation of symptoms.

#### Age

From **40 years** old to **65 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)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellor for Research, Iran university of medical sciences

##### Street address

Hemmat highway

##### City

Tehran

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

8512

## Health conditions studied

### 1

#### Description of health condition studied

Knee Osteoarthritis

#### ICD-10 code

M17.1

#### ICD-10 code description

Other primary gonarthrosis

## Primary outcomes

### 1

#### Description

pain, symptoms, and activities of daily living

#### Timepoint

Before and after treatment

#### Method of measurement

Koos questionnaire

### 2

#### Description

Pain

#### Timepoint

Before and after treatment

#### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The acupuncture group (A): acupuncture at selected acupoint for knee pain, 3 sessions per week for 4 weeks

#### Category

Rehabilitation

### 2

#### Description

The physical modality group (B): TENS (transcutaneous electrical nerve stimulation), ultrasound and hot pack at pain areas, 3 sessions per week for 4 weeks.

#### Category

Rehabilitation

### 3

#### Description

The exercise group (C): isometric exercise of the knee, 3 sessions pr week for 4 weeks

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Firoozgar hospital

##### Full name of responsible person

Dr Bijan Forogh, MD

##### Street address

Behafarin street

**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Iran university of medical sciences

**Full name of responsible person**

Dr Said Abbas Motavalian

**Street address**

Hemmat highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Iran 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**

Iran university of medical sciences

**Full name of responsible person**

Dr Mohammad Saleki, MD

**Position**

Sport medicine resident

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Assistant Professor / Psychiatrist

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## Person responsible for updating data

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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*

