# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effects of hip and knee trigger point dry needling on pain, function and balance in patients with knee osteoarthritis

## Protocol summary

**Summary**

Objective: Pain is a common complication of patients with knee Osteoarthritis.75% of pain in these patients originates from facial tightness and trigger points. Considering positive effects of dry needling, it might be used as an alternate method to decrease pain and improve function of patients with knee Osteoarthritis. Methods and Materials: Forty patients (aged 50-70) with moderate knee Osteoarthritis will participate in this RCT using sample of convenience. Patients will be randomly assigned into either intervention or control group. Inclusion criteria: Knee pain؛ Morning stiffness؛ Crepitation in movement؛ Radiologic signs of osteoarthritis؛ have at least one trigger point on muscles around hip and knee.exclusion criteria: extraction of joint fluid or Corticosteroid injection؛ lower limb or spinal surgery؛ systemic diseases.A written informed consent will be signed by the eligible patients. Our outcome measures are functional level (KOOS questionnaire), pain intensity (visual analogue scale), trigger point sensitivity (algometery), balance (Y- test), and performance (40m fast- paced walk and Timed Up and Go test). After initial assessment, patients in intervention group will receive 3 sessions of dry needling in knee and thigh muscles. The control group will not receive treatment. Secondary evaluation in both groups will be performed seven days after the last session. Results will be analysed to evaluate intra-group and inter-group changes of the outcomes measures.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015020415932N9**
Registration date: **2015-07-01, 1394/04/10**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

**Registration date**

2015-07-01, 1394/04/10

**Registrant information**

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Alireza Motealleh
**Name of organization / entity**
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**Recruitment status**

**Recruitment complete**

**Funding source**
Shiraz University of Medical Sciences

**Expected recruitment start date**

2015-05-22, 1394/03/01

**Expected recruitment end date**

2015-08-23, 1394/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of hip and knee trigger point dry needling on pain, function and balance in patients with knee osteoarthritis

**Public title**

The effects of hip and knee trigger point dry needling on pain & disability of patients with knee arthrosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion Criteria: Patients with moderate knee Osteoarthritis based on Kellgren scale(have knee pain Morning stiffness less than half an hour Crepitation in movement Radiologic signs of Osteoarthritis have at least one trigger point on muscles around hip and knee Age 45-70 Visual Analogue Scale 3-7 Literate Exclusion criteria: Extraction of joint fluid or Corticosteroid injection history of surgery in lower limb or spinal Systemic disease Acute arthritis Soft tissue involvement in Rheumatoid arthritis Acute knee Inflammation Neurologic disease( such as Epilepsy) Anticoagulant use( such as Aspirin) Blood diseases(such as Hemophilia) Acute Immune disease Phobia of needle Lymphedema Malignancies AIDS Hepatitis Heart valve problem Acute infection Cardiovascular disease Pregnancy Intact vestibular system

**Age**

From **45 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand street, Shiraz, Fars, Iran

**City**

Shiraz

**Postal code**

**Approval date**

2015-04-30, 1394/02/10

**Ethics committee reference number**

IR.SUMS.REC.1394.19

## Health conditions studied

**1**

**Description of health condition studied**

Knee Osteoarthritis

**ICD-10 code**

M17.0

**ICD-10 code description**

Primary gonarthrosis, bilateral

## Primary outcomes

**1**

**Description**

Pain

**Timepoint**

before treatment and seven days after last session

**Method of measurement**

Visual analog scale

**2**

**Description**

Function

**Timepoint**

before treatment and seven days after last session

**Method of measurement**

Koos Questionnaire

**3**

**Description**

Balance

**Timepoint**

Before treatment and seven days after last session

**Method of measurement**

Y Balance test

## Secondary outcomes

**1**

**Description**

Performance

**Timepoint**

before treatment and seven days after last session

**Method of measurement**

40m fast paced walk test & timed up and go test

## Intervention groups

**1**

**Description**

The control group will be treated by dry needling 3 sessions (3 days a week) for trigger points around hip and knee joint. After needling, the needle will be moved in different directions to detect muscle twitch.

**Category**

Treatment - Other

**2**

**Description**
The control group will not receive treatment.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
School of Rehabilitation Sciences
**Full name of responsible person**
Najmeh Abdoldhian
**Street address**
**City**
Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Basir Hashemi
**Street address**
Central Building of Shiraz University of Medical Sciences ,Zand avenue ,Shiraz
**City**
Shiraz
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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

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## Person responsible for scientific inquiries

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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*