Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effect of knee joint distraction on the pain and function of patients with severe knee osteoarthritis

Protocol summary

Summary

In this clinical trial 40 patients with sever knee osteoarthritis (grade 3&4 in Kalgren Lawrence scale) with age 45-75 will be recruited. The patients would assign randomly into two groups. In control group the treatment includes routine physiotherapy procedure and in the case group the treatment includes the routine physiotherapy procedure and knee joint distraction. the sustain distraction would be applied for 20 minutes to the level of perception of the patients. The treatments in both groups will be applied for 10 sessions, 5 sessions in each week. The assessments in both groups includes: ROM measurements, the edema measurement and VAS in each session and the KOOS questionnaire and 6 minute walking test before and after 10 treatment sessions and also 1 month after the end of treatment program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111214738N2**
Registration date: **2011-12-28, 1390/10/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-28, 1390/10/07

Registrant information

Name

Khosro Khademi Kalantari

Name of organization / entity

Shahid Beheshti university of medical sciences, Faculty of Rehabilitation

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1411

Email address

k_khademi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-07-11, 1390/04/20

Expected recruitment end date

2012-02-18, 1390/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of knee joint distraction on the pain and function of patients with severe knee osteoarthritis

Public title

the effect of distraction in the treatment of knee arthrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female patients with sever knee OA (grade 3&4 Kalgren Lawrence scale) with the age range between 45 and 75. Exclusion criteria : malignancy in knee joint, infection around the knee joint, metabolic disease, endocrine disorders, vascular disease, injection of corticosteroid in the last 30 days, recent start of use of anti-inflammatory medicine (in the last 30 days), open injuries in the knee, secondary osteoarthritis, history of knee fractures, surgery in the knee joint in the last 6 months, pain duration less than 1 year, knee joint hypermobility and ligamentus laxity, sever edema

around the knee joint and psychological disorders. - Feel of pain in the chest, breathlessness, leg cramps, tumbling, sever perspiration and pale appearance and inability for finishing the 6 minute walking test. -Absence in two successive treatment sessions.

Age
From **45 years** old to **75 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
shahid Beheshti university of medical sciences

Street address
Daneshjoo Ave, Evin

City
Tehran

Postal code

Approval date
2011-10-30, 1390/08/08

Ethics committee reference number
108

Health conditions studied

1

Description of health condition studied
knee osteoarthritis

ICD-10 code
M19.0

ICD-10 code description
Primary arthrosis NOS

Primary outcomes

1

Description
functional ability

Timepoint
in the 1st session, 10th session and 1 month after treatment ends

Method of measurement
by 6 minute walking test

2

Description
amount of pain

Timepoint
in 1st to 10th session and 1 month after treatment ends

Method of measurement
by VAS measurement

3

Description
amount of joint effusion

Timepoint
in 1st to 10th session and 1 month after treatment ends

Method of measurement
by measurement tape over and 10 cm above and bellow knee joint line

4

Description
knee joint mobility

Timepoint
in 1st to 10th session and 1 month after treatment ends

Method of measurement
by goniometer

Secondary outcomes

1

Description
quality of life

Timepoint
in 1st and 10th session and 1 month after treatment ends

Method of measurement
questionnaire

Intervention groups

1

Description
Control group : US, TENS, HOTPACK and EXERCISEUS is applied for 5 minutes to anterior, posterior knee in each session for ten sessions Conventional TENS is applies for 20 minutes in each session for 10 sessions2 hot packs are applied to anterior and posterior knee for 20 minutes

in each session and for 10 sessions.2 exercises are trained to patients in 1st session

Category

Rehabilitation

2

Description

case group interventions: US, TENS, HOTPACK and EXERCISE + distractionUS is applied for 5 minutes to anterior, posterior knee in each session for ten sessionsConventional TENS is applies for 20 minutes in each session for 10 sessions2 hot packs are applied to anterior and posterior knee for 20 minutes in each session and for 10 sessions.2 exercises are trained to patients in 1st sessionSustain joint distraction is applied for 20 minutes in each session for 10 sessions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar clinic

Full name of responsible person

Somaye Mahmoodi Aghdam

Street address

17 shahrivar clinic, pol station, damavand Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Bbeheshti University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr. Rahmati Roodsari

Street address

Daneshjoo Ave, Evin

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Bbeheshti University of Medical Sciences, Vice Chancellor for Research

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

Faculty of rehabilitation, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somaye Mahmoodi Aghdam

Position

MSc student

Other areas of specialty/work

Street address

Damavand Ave, Faculty of rehabilitation

City

Tehran

Postal code

Phone

+98 21 7756 1411

Fax

Email

smahmoodiaghdam@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Rehabilitation, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Khosro Khademi Kalantari

Position

Associate Professor/PhD

Other areas of specialty/work

Street address

Damavand Ave, Faculty of Rehabilitation

City

Tehran

Postal code

Phone

+98 21 7756 1411

Fax

Email

k_khademi@sbmu.ac.irkhosro_khademi@yahoo.co.uk

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Rehabilitation, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Khosro Khademi Kalantari

Position

PhD

Other areas of specialty/work

Street address

Damavand Ave

City

Tehran

Postal code

Phone

+98 21 7756 1411

Fax

Email

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