

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

comparison of intra articular prolotherapy versus peri articular prolotherapy on decreasing pain and improvement of the function in patient with knee osteoarthritis

Protocol summary

Summary

Knee osteoarthritis (KOA) is a common disabling disease. Limited studies have demonstrated that prolotherapy intra-articular or peri-articular be helpful in the treatment of patients with KOA. In the current study, we compared the results between these two treatment methods. In the current randomized clinical trial, 25 patients with KOA were randomly assigned equally into two groups (intra-articular group and peri-articular group). In each group, injections were repeated two times with 10-14 day intervals. Before the treatment and 2 and 4 weeks after the injections, the pain intensity was measured by using a visual analogue scale and the Western Ontario and McMaster university arthritis index scores(WOMAK) and oxford knee scale (OKS)Finally, the results were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091229795N1**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Farzane Fereydooni

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2017-06-30, 1396/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of intra articular prolotherapy versus peri articular prolotherapy on decreasing pain and improvement of the function in patient with knee osteoarthritis

Public title

Evaluation of the effectiveness of prolotherapy on patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patient had these symptoms atleast for 1 month joint stiffness; criptation; knee pain.
exclusion criteria: any intra or extra knee joint injection in past 3 months; total knee arthroplasty; lumbo sacral radiculopathy; uncontrolled diabetic mellitus with HbA1C more than7.5; reumatic disorders such as rheumatoid arthritis,goat, SLE, brucella; knee truma during 3 months

ago; knee fracture during 3 months ago; BMI more than 42.

Age

From **38 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science, Central department, Zand street, Shiraz

City

Shiraz

Postal code

Approval date

2016-07-26, 1395/05/05

Ethics committee reference number

ir.sums.med.rec.1395.33

Health conditions studied

1

Description of health condition studied

arthrosis of knee

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

2

Description of health condition studied

arthrosis of knee

ICD-10 code

M17.1

ICD-10 code description

Other primary gonarthrosis

Primary outcomes

1

Description

pain

Timepoint

before injection, 2 and 4 weeks after injection

Method of measurement

Visual Analog Scale(VAS)

2

Description

patient function

Timepoint

before injection and 2 and 4 weeks after injection

Method of measurement

The WOMAC consists of 24 items divided into 3 subscales:Pain (5 items): during walking, using stairs, in bed, sitting or lying, and standing.Stiffness (2 items): after first waking and later in the day.Physical Function (17 items): stair use, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet, heavy household duties, light household duties

Secondary outcomes

empty

Intervention groups

1

Description

in first group patient lies at bed, patient's knee with placing a pillow under it flexes to 30 degrees then practitioner prep the knee and injects 5 cc dextrose 25% from inferiolateral side of the knee joint by 23 gauge Syringe. Preparation of dextrose 25%(2.5 cc lidocaine2% plus 2.5 cc dextrose 50%)

Category

Treatment - Drugs

2

Description

In second group injects 5cc dextrose 25 % by using 25 gauge syringe around knee joint maximum in two points (lateral or medial) that is the most painful, except pesanserine bursitis. Preparation of dextrose 25%(2.5 cc lidocaine2% plus 2.5 cc dextrose 50%)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajai Hospital

Full name of responsible person

Freydooni farzane

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Emam Raza Clinic

Full name of responsible person

Fereydooni Farzane

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Physical Medicine and Rehabilitation

Full name of responsible person

Davatgar mrs

Street address

Department of Physical Medicine and Rehabilitation,
Second floor, Faghihi Hospital, Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Department of Physical Medicine and Rehabilitation

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

Department of Physical Medicine and Rehabilitation

Full name of responsible person

Fereydooni Farzane

Position

Resident of Rhyssal Medicine and Rehabilitation

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Department of Physical Medicine and Rehabilitation

Full name of responsible person

Far por Hamid reza

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Assistant professor of Physical Medicine and
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Other areas of specialty/work

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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