

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effectiveness of intra-articular prolotherapy versus peri-articular prolotherapy on pain reduction and improving function in patients with knee osteoarthritis without effusion

Protocol summary

Study aim

Comparison of the Intra-articular Prolotherapy versus Peri-articular Prolotherapy on pain reduction and improving of function in patients with knee osteoarthritis without effusion

Design

Blocked randomized, two ways, blinded parallel clinical trial

Settings and conduct

60 eligible patients with knee osteoarthritis without effusion who were referred to Physical Medicine and Rehabilitation Clinics of Shiraz University of Medical Sciences, will be randomly assigned to two parallel treatment groups, A: Intra-articular prolotherapy and B: Peri-articular prolotherapy. Patients after receiving informations and signing informed consent form, will complete demographic, VAS, WOMAC and OKS questionnaires. Then, based on the allocated group, they will get specified treatment twice, within 2 weeks. Patients will complete the questionnaires in the 4th and 8th week based on the first injection. Patients and data analyzer will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient suffering from joint stiffness; criptation; knee pain for at least for 3 month. Exclusion criteria: any intra or extra knee joint injection in the past 3 months; total knee arthroplasty; lumbosacral radiculopathy; uncontrolled diabetic mellitus with HbA1C more than 7.5%; rheumatic disorders; knee trauma during 3 months ago; knee fracture during 3 months ago; BMI over 42.

Intervention groups

The first group involve the patients with knee osteoarthritis without effusion that will undergo intra-articular injection. The second group involve the patients with knee osteoarthritis without effusion that will undergo peri-articular injection

Main outcome variables

Pain, Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171111037396N1**

Registration date: **2018-07-18, 1397/04/27**

Registration timing: **prospective**

Last update: **2018-07-18, 1397/04/27**

Update count: **0**

Registration date

2018-07-18, 1397/04/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 737 9584

Email address

dashtimakan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of intra-articular prolotherapy versus peri-articular prolotherapy on pain reduction and improving function in patients with knee osteoarthritis without effusion

Public title

Prolotherapy in Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Negative Ballottement test Negative Fluid wave test Age from 38 years old to 70 years old of both sex Diagnosed as knee osteoarthritis according to clinical criteria of American College of Rheumatology Having grade 2 and 3 based on Kellgren and Lawrence Grading Scale Complain of pain, crepitation and knee joint stiffness that lasted at least three months before study

Exclusion criteria:

Foot deformity Sever genu valgum Any infection involving the knee skin Any intra or peri articular injection during the three last months History of rheumatic or inflammatory disease involving the knee joints Prior total knee arthroplasty Poorly controlled DM with HbA1c more than 7.5% BMI more than 42 History of knee trauma or fracture during the three last months History of acute lumbosacral radiculopathy or peripheral neuropathy History of cancer Bleeding disorders Pregnancy Severe genu varum

Age

From **38 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly allocate 60 eligible subjects to two parallel groups: Intra-articular injection as group A and Peri-articular injection as group B by the administrator of the clinician who educated to use a block randomization list. The list is made by computer as non-stratified list, with the equal block length. The patients will be not aware of being allocated in the group A or B. Also, statisticians will be kept blind about the allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be allocated by blocked randomization list to 2 groups by investigator A :Intraarticular

prolotherapy and B:Periarticular prolotherapy. the patients will be not aware of being allocated in the group A or B. In both groups the investigator will inject the prolotherapy agent.The patients will be visited by a second colleague who will be not aware of the groups during the study.outcome assessor will be not blind but statisticians will be kept blind about the allocation.

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 Sciences, Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

IR.SUMS.MED.REC.1397.88

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes**1****Description**

Pain

Timepoint

Before injection, 4 and 8 weeks after injection

Method of measurement

Visual Analog Scale (VAS)

2

Description

Function

Timepoint

Before injection and 2 and 4 weeks after injection

Method of measurement

The WOMAC consists of 24 items divided into 3 sub scales : 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 the group A patient lies on bed, patient's knee with placing a pillow under it flexes to 30 degrees then practitioner prepare 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 lidocaine 2% plus 2.5 cc dextrose 50%)

Category

Treatment - Drugs

2

Description

In the group B, 5 cc of dextrose 25% will be injected by using 25 gauge syringe around knee joint maximum in two points (lateral or medial). These points are the most painful points, except pesanserine bursitis. Preparation of dextrose 25% (2.5 cc lidocaine 2% plus 2.5 cc dextrose 50%)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

Dashtimakan Hadi

Street address

Rajae Hospital, Chamran Blvd., Shiraz

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2

Recruitment center

Name of recruitment center

Emam Raza Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd. Shiraz, Iran

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dashtimakan Hadi

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Rooshanzamir Sharareh

Position

Assistant Professor of Physical Medicine and
Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Medical intern

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available