

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 Function Improvement in Patients with Knee Osteoarthritis with Effusion

Protocol summary

Study aim

Comparison of the effectiveness of intra-articular prolotherapy versus peri-articular prolotherapy on pain reduction and function improvement in patients with knee osteoarthritis with effusion

Design

Two ways randomized blinded parallel clinical trial with 60 participants

Settings and conduct

60 eligible patients with knee osteoarthritis with 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, Intra-articular prolotherapy and Peri-articular prolotherapy. Patients after receiving informations and signing informed consent form, will complete demographic, VAS, WOMAC questionnaires. They will get specified treatment twice, within 2 weeks. Patients will complete the questionnaires in the 4th and 8th week after the first injection. Patients and data analyzer will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with knee osteoarthritis with effusion, aged between 38 to 70 years; both sex; complaining of knee pain; knee crepitation and knee joint stiffness at least for three months before study. Exclusion criteria: having foot deformity; sever Genu Valgum; any infection affecting the knee skin; intra or peri articular injection or knee trauma or fracture for the last three months before the study; knee joints rheumatic or inflammatory disease; total knee arthroplasty; uncontrolled diabetes with HbA1c more than 7.5%; BMI more than 42; acute lumbosacral radiculopathy or peripheral neuropathy; cancer; bleeding disorders; pregnancy; severe Genu Varum.

Intervention groups

Patients with knee osteoarthritis with effusion will

allocate into two groups. The first group drug will be injected in the joint, the second group drug will be injected in specified points around the joint.

Main outcome variables

Pain; Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180623040209N1**

Registration date: **2018-08-04, 1397/05/13**

Registration timing: **prospective**

Last update: **2018-08-04, 1397/05/13**

Update count: **0**

Registration date

2018-08-04, 1397/05/13

Registrant information

Name

Pouria Aminsafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

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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 Function Improvement in Patients with Knee Osteoarthritis with Effusion

Public title

Prolotherapy in Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Negative Ballottement Test Negative Fluid Wave Test Age from 38 to 70 years in both sexes Suffering from Knee Osteoarthritis with effusion based on clinical criteria of American College of Rheumatology Suffering from grades 2 and 3 of Knee Osteoarthritis based on Kellgren and Lawrence Grading Scale Complain of knee pain at least for three months before study Knee crepitation at least for three months before study Knee joint stiffness at least for three months before study

Exclusion criteria:

Foot deformity Sever Genu Valgum Any infection affecting the knee skin Any intra or peri articular injection for the last three months before the study History of knee joints rheumatic or inflammatory disease History of total knee arthroplasty Uncontrolled diabetes with HbA1c more than 7.5% BMI more than 42 History of knee trauma or fracture for the last three months before the study 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
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocate in two groups using random number table and will adjust by age and sex.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will randomly allocate into two groups using

random number table, while the researcher is blind about the groups. Also, patients are blinded about the group which they were allocated. After the applying the treatment, while assessing the outcomes and analyzing data, the interviewer of outcomes and the analyzing team will be blinded about the groups, respectively.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of School of Medicine, Shiraz University of Medical Sciences

Street address

School of Medicine, Shiraz University of Medical Sciences, Zand blvd.

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

IR.SUMS.MED.REC.1397.089

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 first injections, 4 and 8 weeks after first injection

Method of measurement

Visual Analog Scale (VAS)

2

Description

Function

Timepoint

Before first injections, 4 and 8 weeks after first injection

Method of measurement

The WOMAC questionnaire 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 first group patients lies on bed, patient's knee with placing a pillow under it flexes to 30 degrees then practitioner prepare the knee and injects 8 ml of 10% hyper tonic dextrose with 2 ml of 2% Lidocaine will be injected in the joint and the injection will repeat two weeks later.

Category

Treatment - Drugs

2

Description

In the second group patients lies on bed, patient's knee with placing a pillow under it flexes to 30 degrees then practitioner prepare the knee and 5 ml of 20% hyper tonic dextrose with 5 ml of 1% Lidocaine will be injected in specified points around the joint and the injection will repeat two weeks later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

Pooria Amin Safaei

Street address

Rajae Hospital, Chamran Blvd.

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2

Recruitment center

Name of recruitment center

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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

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

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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

Pooria Amin Safaei

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

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Full name of responsible person

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Person responsible for updating data

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Position

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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