Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 arthtoplasty; 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)
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+98 71 3230 5410
Email address
aminsafaei@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 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 Kellgern 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 arthtoplasty 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 weaks 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 weaks later.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
Pooria Amin Safaei
Street address
Rajaee Hospital, Chamran Blvd.
City
Shiraz
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Postal code
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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.
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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

Street address

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Rooshanzamir Sharareh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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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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