Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 than7.5%; 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 Kellgern 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 arthtoplasty 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
Befor 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 lidocaine2% 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 lidocaine2% plus 2.5 cc dextrose 50%)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
Dashtimakan Hadi
Street address
Rajaee 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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vcrdep@sums.ac.ir
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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Specialist

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Physical Medicine

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Person responsible for updating data

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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