Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Investigation of the Effect of Concomitant Intraarticular and Periarticular Prolotherapy in Comparison to Intraarticular Prolotherapy in Knee Osteoarthritis without effusion on Pain and Functional Limitation.

Protocol summary

Study aim

Determine the average of the VAS score for the initial visit and before starting the treatment in both groups. Determine the average VAS score after the last injection and in weeks 2 and 4 in each group. Comparison of average VAS score in both groups before and after treatment. Determine the average WOMAC score for joint pain in various routine activities in the initial visit and before starting treatment in both groups. Determine the average WOMAC score for joint stiffness in the initial visit and before starting treatment in each group. Determine the average score of WOMAC for the daily functions in the initial visit and before starting treatment in both groups. Determine the average WOMAC score for joint stiffness after the last injection and in weeks 2 and 4 in both groups. Determine the average score of WOMAC for the daily functions after the last injection and in weeks 2 and 4 in both groups. Comparison of the average WOMAC score for joint pain in various routine activities in both groups before and after the last injection and at weeks 2 and 4. Comparison of average WOMAC score of joint stiffness in both groups before and after the last injection and in weeks 2 and 4. Comparison of the average WOMAC score of the daily functions in both groups before and after the last injection and at weeks 2 and 4. Determine the average of the OKS score. Ability to perform various activities in the initial visit and before starting treatment in both groups. Determine the average of the OKS score. Ability to perform various activities after the last injection and in weeks 2 and 4 in both groups. Comparison of the average of the OKS score. Ability to perform different activities in both groups before and after the last injection and in weeks 2 and 4.

Design

The study population consisted of 112 patients with a history of knee pain due to osteoarthritis that causes pain and fatigue, functional limitation, decrease range of motion , which was detected by plain radiography, were randomly divided into two groups: A and B (56 People in each group). Demographic characteristics of both groups in terms of age, sex, type and joint destruction (on The basis of radiological standards is similar). To randomize the study, a randomized block method is used.

Settings and conduct

This is a randomized clinical trial that was conducted on referrals to physicians and rehabilitation clinics of Shiraz University of Medical Sciences - Imam Reza Clinic (AS) and Shahid Chamran and Shahid Rajaee Hospitals.

Participants/Inclusion and exclusion criteria

The criteria for entering the study were: completing informed consent; the presence of pain and other clinical symptoms of knee osteoarthritis in the last month; age between 45-70 years old; and the absence of any disease around the relevant joint. Exclusion criteria: diabetes, rheumatic diseases and collagen and vascular disease, gout and lupus, radiculopathy, nerve injury and neuropathy; Brucella infection; BMI> 42; history of knee replacement on the affected side; bleeding disorder; inability to communicate and complete questionnaires; history of allergy and allergic reaction to used drugs; history of significant liver, kidney and cardiovascular disorders; history of injections inside or around the joint in the last 3 months; pregnant women; people who have cancer; people who are on the go use of anticoagulants.

Intervention groups

Treatment in group A includes intra-articular and periarticular injection of 3 ml saline 5% plus 3 ml Lidocaine 2% along with advice on observing the correct way of life and exercising proper knee pain that is help to them. Group B treatment includes intra-articular injection of 3 ml of saline 5% plus 3 ml of lidocaine 2% plus recommendation to Observing the right way of life and doing proper knee pain exercises that are help to them. For each of the two groups, 3 injection steps are performed within 2 weeks.

Main outcome variables
More possible improvements in the symptoms of osteoarthritis in patients with intra-articular and periarticular prolotherapy in comparision intra-articular prolotherapy alone, in knee osteoarthritis with effusion.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180106038229N1**
Registration date: **2018-11-27, 1397/09/06**
Registration timing: **retrospective**

Last update: **2018-11-27, 1397/09/06**
Update count: **0**
Registration date
2018-11-27, 1397/09/06

Registrant information
Name
Reza Soleymani asl
Name of organization / entity
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Phone
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2018-11-22, 1397/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the Effect of Concomitant Intraarticular and Periarticular Prolotherapy in Comparison to Intraarticular Prolotherapy in Knee Osteoarthritis without effusion on Pain and Functional Limitation.

Public title
Investigation of the Effect of Concomitant Intraarticular and Periarticular Prolotherapy in Comparison to Intraarticular Prolotherapy in Knee Osteoarthritis without effusion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Completing informed consent Presence of pain and other clinical symptoms of knee osteoarthritis in the last month
Exclusion criteria:
Diabetes, rheumatic diseases and collagen and vascular disease Gout and lupus, radiculopathy, nerve injury and neuropathy Brucella infection BMI> 42 History of knee replacement on the affected side, Bleeding disorder, inability to communicate and complete questionnaires History of allergy and allergic reaction to used drugs History of significant liver, kidney and cardiovascular disorders History of injections inside or around the joint in the Last 3 months Pregnant women People who have cancer People who are on the go Use of anticoagulants
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **112**
More than 1 sample in each individual
Number of samples in each individual: **1**
One knee or both knees can be used in the study.
Randomization (investigator's opinion)
Randomized
Randomization description
In the randomization process, the envelopes containing letters A and B are used so that the letters inside the envelopes are not recognizable from the outside, as well as the manner in which the envelopes are placed randomly in succession and the person present at the time The randomization of content and the ordering of information in envelopes is not known.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants, assessing the outcome and analyzing the data, do not know which patient is in the treatment group and only the patients are known under the names of groups A and B.
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

Central Building of Shiraz University of Medical Sciences, opposite Palestine Street, Zand Ave., Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-05-18, 1397/02/28

Ethics committee reference number

IR.SUMS.MED.REC.1397.218

Health conditions studied

1

Description of health condition studied

Osteoarthritis, effusion, knee, prolotherapy

ICD-10 code

M15.9

ICD-10 code description

Generalized osteoarthritis NOS

Primary outcomes

1

Description

Individuals with knee joint osteoarthritis without effusion accopmpanied by pain.

Timepoint

In both groups before treatment and 2 weeks after the last injection

Method of measurement

The standard questionnaire of VAS, WOMAC, OKS, which is one of the most commonly used outcome measures in the treatment of knee osteoarthritis, was completed. VAS For pain levels, WOMAC is used to check the pain in everyday activities. OKS is also used to assess the amount of pain and the ability to perform various activities.

2

Description

Individuals with knee joint osteoarthritis without effusion accopmpanied by limitation of motion of knee joint.

Timepoint

In both groups before treatment and 2 weeks after the last injection

Method of measurement

The standard questionnaire of VAS, WOMAC, OKS, which is one of the most commonly used outcome measures in the treatment of knee osteoarthritis, was completed. VAS For pain levels, WOMAC is used to check the pain in everyday activities. OKS is also used to assess the amount of pain and the ability to perform various activities.

3

Description

Individuals with knee joint osteoarthritis without effusion accopmpanied by knee joint stiffness.

Timepoint

In both groups before treatment and 2 weeks after the last injection

Method of measurement

The standard questionnaire of VAS, WOMAC, OKS, which is one of the most commonly used outcome measures in the treatment of knee osteoarthritis, was completed. VAS For pain levels, WOMAC is used to check the pain in everyday activities. OKS is also used to assess the amount of pain and the ability to perform various activities.

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group number 1, intra-articular injection was performed alone in patients with knee osteoarthritis. In this intervention, 3 cc saline solution 5% and 2 cc of lidocaine 2% were used as a prothotelapy technique Intra-articular injection is performed once a week, and in general, 3 injections are performed within 1 week intervals. Before the intervention, standard variables were evaluated by the Persian standard questionnaire and then 2 weeks after the last Injection of different variables is evaluated again by standard Farsi questionnaires.

Category

Treatment - Other

2

Description

In the intervention group number 2, intra-articular and peri-articular injection was performed in patients with knee osteoarthritis. In this intervention, 3 cc of 5% saline solution with 2 cc of lidocaine 2% was used as a orolotherapy technique. Intra-articular and peri-articular injections are performed once a week, and in general, three injections are performed within 1 week intervals. Before the intervention, standard variables were evaluated by the fasi standard questionnaire and then 2 The week after the last injection of different variables was again re-examined by standard Farsi questionnaires Is evaluated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Reza Soleymani Asl
Street address
Imam Reza Clinic., Zand Blvd., Shiraz
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Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3212 7001
Email
emamreza@sums.ac.ir

2

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Reza Soleymani Asl
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Fars
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Phone
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Email
chamhosp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sharareh Roshanzamir
Street address
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Email
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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
Sharareh Roshanzamir
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Rehabilitation management
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Person responsible for scientific inquiries

Contact
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Position
Medical Student
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

En The forced publication law relates to plans for the year 97. Regarding the fact that our plan will be implemented in year 96, it will be editorial according to the editor's request only if the editor of the journal publishes the paper.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available