Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effect of concomitant intraarthicular and periarticular prolotherapy in comparison to intraarticular prolotherapy in knee osteoarthritis with effussin in Reduce pain and improve function

Protocol summary

Study aim

Further possible improvements in the symptoms of Osteoarthritis in patients after perform intra-Prolotherapyand round- Prolotherapyjoint compared with intra-joint alone with using Effusion.

Design

The study population that consist of 40 patients with history of knee joint pain that cause pain and fatigue, performance limitation, that has decreased joint range and cause Osteoarthritis which is detected by simple radiography as a random block (blocks four) are divided into two groups, A and B(20 person in each group), and a double-blind study.

Settings and conduct

The study population that consist of 40 patients with history of knee joint pain that cause pain and fatigue, performance limitation, that has decreased joint range and cause Osteoarthritis which is detected by simple radiography as a random block (blocks four) are divided into two groups, A and B(20 person in each group), and a double-blind study.

Participants/Inclusion and exclusion criteria

Entry conditions: The presence of pain and other clinical symptoms of knee Osteoarthritis in a recent month; Age between 40-70 years; Exit criteria: Diabetes; Rheumatic diseases, Collagen, Vascular, Gout and Lupus; Overlap Radiculopathy; Nerve damage and Neuropathy; Brucella; Body mass index above 42; History of knee joint replacement

Intervention groups

In each injection group performed at 3 points where the pain is most severe. In A group, first, 3 ml of Effusionisdrawnintravenous into joint and injection3ml of drug intra-joint, 3 ml of drug round joint and group B, first, 6 ml of Effusion is drawn, and then 6ml of drug is injected into joint. The drug, mixtures of 3ml of Saline5%, plus 3ml Lidocaine 2%, plus a recommendation to observe the correct way of life and exercise proper knee pain that is taught to them. For each group, 3 steps injection take place within 2 weeks.

Main outcome variables

VAS score WOMAC score OKS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171215037873N1**
Registration date: **2018-05-06, 1397/02/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-06, 1397/02/16**
Update count: **0**

Registration date

2018-05-06, 1397/02/16

Registrant information

Name

Fatemeh Doroudi Doroudzani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3725 3171

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effect of concomitant intraarthicular and periarticular prolotherapy in comparison to intraarticular prolotherapy in knee osteoarthritis with effussin in Reduce pain and improve function

Public title
The effect of prolotherapy on knee joint wear with effusion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The criteria for entering the study were completing sompleting form of consent, the presence of pain and other clinical symptoms of knee osteoarthritis in the last month
Exclusion criteria:
Exculusion 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 3 Last month, pregnant women, people who have cancer, people who are on the go Use of anticoagulants.
Age
From **40 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: **40**
More than 1 sample in each individual
Number of samples in each individual: **0**
One knee or both knees can be used in the study.
Randomization (investigator's opinion)
Randomized
Randomization description
Patient 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.
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
2017-11-06, 1396/08/15
Ethics committee reference number
IR.SUMS.MED.REC.1396.99

Health conditions studied

1

Description of health condition studied
Osteoarthritis, effusion, knee, prolotherapy
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
People with knee osteoarthritis with effusion
Timepoint
In both groups before and after treatment in weeks 2 and 4 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

1

Description
Knee pain recovery, improvement of individual performance in life
Timepoint
In both groups before and after treatment in the 2nd and 4th weeks after the last injection, 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.
Method of measurement
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.

Intervention groups

1

Description
Intervention group: Intraarthicular and periarticular prolotherapy and Intraarthicular prolotherapy
Category
Treatment - Other

2

Description
Intervention group: Intra-articular prolotherapy and intra-articular and periarticular prolotherapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic, Chamran Hospital and Rajai Hospital
Full name of responsible person
Fatemeh Doroudi Doroudzani
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Modarres Blvd., Shahid Kalantari St., Alley 27, No. 291
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Sponsors / Funding sources

1

Sponsor
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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
Assistant Professor
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Person responsible for updating data

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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
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