Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of the effectiveness of dextrose prolotherapy vs. genicular nerve block in reducing pain and improving function in patients with knee osteoarthritis

Protocol summary

Study aim
Comparison of dextrose prolotherapy with genicular nerve block with alcohol in reducing pain and improving function in patients with knee osteoarthritis

Design
The research is a randomized double blind clinical trial on 60 patients

Settings and conduct
Samples are selected from patients with knee osteoarthritis referred to Imam Reza Clinic and Rajaei Hospital and are divided into two groups. For randomization of the study, the blocked randomized method is used. after obtaining inform consent, in the control group, prolotherapy with 25% dextrose will be administered intraarticularly in 3 stages (one week apart) and in the intervention group, three branches of genicular nerves (supramedial, supralateral and inframedial) will be blocked in one stage and finally the effects on pain reduction and functional improvement will be measured

Participants/Inclusion and exclusion criteria
Inclusion criteria: Existence of pain and clinical signs of knee osteoarthritis and VAS score of at least 4 due to knee osteoarthritis during last month Age between 45 to 70 years old Absence of any periarticular disease around the target joint Exclusion criteria: Diabetes Mellitus Rheumatologically and collagen vascular disorders Gout Lupus Radiculopathy Nerve injuries and neuropathy Brucellosis BMI more than 42 Knee replacement on the affected side History of trauma and joint fracture Severe deformity of the lower extremities Bleeding disorders History of allergic reactions to the used drugs History of intraarticular or periarticular injections at the affected joint in the last 3 months History of significant liver, kidney and cardiopulmonary disorders Pregnancy Malignancy Use of anticoagulants

Intervention groups
Group A undergoes intra-articular prolotherapy with 25% dextrose in 3 stages and group B under block of three branches of the genicular nerves

Main outcome variables
Pain, Activity of daily living

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201013049018N1**
Registration date: **2021-04-07, 1400/01/18**
Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**
Update count: **0**

Registration date
2021-04-07, 1400/01/18

Registrant information

Name
Mohammad Esmaeil ghorbani nejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3639 6445

Email address
mghorbani@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-20, 1400/02/30

Expected recruitment end date
2021-12-21, 1400/09/30

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

Scientific title
The comparison of the effectiveness of dextrose prolotherapy vs. genicular nerve block in reducing pain and improving function in patients with knee osteoarthritis

Public title
"The effectiveness of dextrose prolotherapy in knee osteoarthritis"; "The effectiveness of genicular nerve block in knee osteoarthritis"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of pain and other clinical signs of knee osteoarthritis and pain with a VAS score of at least 4 due to knee osteoarthritis during last month Age between 45 to 70 years old Absence of any periarticular disease around the target joint
Exclusion criteria:
Diabetes Mellitus Rheumatologically and collagen vascular disorders (eg; gout and lupus) Radiculopathy Nerve injuries and neuropathy Brucellosis BMI more than 42 Knee replacement on the affected side History of trauma and joint fracture Severe deformity of the lower extremities Bleeding disorders Inability to communicate History of allergic reactions to the used drugs History of intraarticular or periarticular injections at the affected joint in the last 3 months History of significant liver, kidney and cardiopulmonary disorders Pregnancy Malignancy Use of anticoagulants
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each knee in each patient can be a sample
Randomization (investigator's opinion)
Randomized
Randomization description
To match patients in the control and treatment groups, patients are randomly assigned to one of two treatment groups. The random allocation method in this study will be the permutation block randomization method, such that "A" represents the subject receiving the prolotherapy method, and "B" represents the subject who receives the genicular nerve block. This method is based on 15 blocks in 4 permutations, taking into account all possible quadruple permutations (AABB, ABAB, ABBA, BAAB, BBAA and BABA) and assigning zero to nine (according to a random number table) to each of these permutations (i.e. AABB Code 0, BABA Code 1, AABB Code 2, BBAA Code 3, BAAB Code 4, and ABBA Code 5 to 9). The method of using random table is that the 15 numbers from zero to nine (rows or columns) are randomly selected, and the assigned permutations to each number are written. (The order of placing permutations next to each other is left to right respectively) and how all 60 people will be assigned to two groups A and B, and so we will have two lists of 30 patients, including the two intervention and control groups, at random. For concealment, this method of random sequencing is given to another person who is unaware of the research process, and the questionnaires are completed by this person unaware of the division of groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participant: At this study, we are not able to blind the patient, because patients of both groups are aware of the type of the intervention. Clinical caregiver: The caregiver is trained to complete the questionnaire and has no knowledge of the type of patient intervention. Researcher: at this study, we do not have the ability to blind the researcher, because the researcher does both studies himself and is aware of the type of intervention in each group. The impact assessor: Completed questionnaires are given to a person who is not aware of the interventions performed and he/she is asked to determine the amount of pain reduction and functional increasement in each person according to the questionnaire. Data analyzer: The questionnaires are finally given to a person to review the information after completing and collecting all the information. This person does not know any of the steps of the work and how to divide the intervention.
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
No. 82, Sepideh Tower, Baneshi Street, Parastar Blvd.,

Ehsan Square

City
Shiraz

Province
Fars

Postal code
7184876856

Approval date
2020-08-17, 1399/05/27

Ethics committee reference number
IR.SUMS.MED.REC.1399.295

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis; Dextrose Prolotherapy; Genicular Nerve Block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain due to knee osteoarthritis

Timepoint
Before starting the intervention; 2, 4, 8, &12 weeks later

Method of measurement
Visual analog scale; Western Ontario and McMaster Universities Arthritis Index; Oxford knee scale; Patient satisfaction

Secondary outcomes

1

Description
Patient function

Timepoint
Before starting the intervention; 2, 4, 8, &12 weeks later

Method of measurement
Visual analog scale

2

Description
Patient function

Timepoint
Before starting the intervention; 2, 4, 8, &12 weeks later

Method of measurement
Western Ontario and McMaster Universities Arthritis Index

3

Description
Patient function

Timepoint
Before starting the intervention; 2, 4, 8, &12 weeks later

Method of measurement
Oxford knee scale

Intervention groups

1

Description
Intervention group: The group undergoing the block of three branches of the genicular sensory nerves (supramedial, supralateral and inframedial branches) in one session (common technique), using 1 cc of Razi company 70% alcohol under the guidance of ultrasound or fluoroscope and correcting lifestyle and doing proper knee exercises

Category
Rehabilitation

2

Description
Control group: The group undergoing prolotherapy with Shahid Ghazi company 25% dextrose intraarticularly by needle (gauge 22) in 3 stages (one week apart) according to the usual protocol with the recommendation to follow the correct lifestyle and perform appropriate knee exercises

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam reza rehabilitation clinic

Full name of responsible person
Mani Ramzi

Street address
Namazi Square

City
Shiraz

Province
Fars

Postal code
714737-71348

Phone
+98 71 3212 7700

Email
motahari@sums.ac.ir

2

Recruitment center

Name of recruitment center
Rajaee hospital

Full name of responsible person
Amirreza Mesbahi

Street address
Chamran Blvd

City

Shiraz
Province
Fars
Postal code
7194815711
Phone
+98 71 3636 4001
Email
Rajaeehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Front of Maaref school; Khalili Avenue
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3628 1506
Email
Info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Mohammad Esmaeil Ghorbani Nejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 82, Sepideh Tower, Baneshi Street, Parastar Blvd., Ehsan Square
City
Shiraz
Province
Fars
Postal code
7184876856
Phone
+98 71 3639 6445
Email
m_ghorbani1990@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Esmaeil Ghorbani Nejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 82, Sepideh Tower, Baneshi Street, Parastar Blvd., Ehsan Square
City
Shiraz
Province
Fars
Postal code
7184876856
Phone
+98 71 3639 6445
Email
m_ghorbani1990@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Esmaeil Ghorbani Nejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 82, Sepideh Tower, Baneshi Street, Parastar Blvd., Ehsan Square
City
Shiraz
Province

Fars

Postal code

7184876856

Phone

+98 71 3639 6445

Email

m_ghorbani1990@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All available data can be shared after making people unidentifiable

When the data will become available and for how long

start access period one year after publishing the results

To whom data/document is available

everyone can access to this information

Under which criteria data/document could be used

if the information in this study helps to improve the science process

From where data/document is obtainable

Dr. Mohammad Esmaeil ghorbani nejad 00989164168766 m_ghorbani1990@yahoo.com

What processes are involved for a request to access data/document

after sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of the three weeks if permitted.

Comments