Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Prolotherapy with Hypertonic Dextrose in Patients with Osteoarthritis of the Knee: A Randomized Clinical Trial

Protocol summary

Study aim
Pain reduction and improving function and quality of life in patients with osteoarthritis of the knee after prolotherapy

Design
Clinical trial with control group, parallel groups, triple blind, randomized, phase 3 on 80 patients.
Randomization by table random number and Clinical C software.

Settings and conduct
Patients referred to the clinic of Ghaem and Imam Reza hospitals and professors' offices in Mashhad

Participants/Inclusion and exclusion criteria
Major inclusion criteria before randomization: all patients with mild to moderate knee osteoarthritis aged 45-75 years according to Kellgren-Lawrence criteria and rheumatologist approval; absence of rheumatic diseases such as Rheumatoid Arthritis; pain and tenderness of the knee joint resistant to medicine and conservative therapy for 3 months. Major exclusion criteria before randomization: pregnancy; allergy to Oxycodone and Lidocaine; 40kg/m2<BMI; history of previous prolotherapy; loosening of ligaments and knee joint; history of diabetes; history of hematologic disease especially with thrombocytopenia; history of taking anticoagulants such as Plavix and warfarin; history of joint injection in the last 3 months; history of inflammatory joint disease and history of knee joint infection; people who are candidates for knee surgery with grade 4 based on Kellgren-lawrence; history of joint replacement and presence of joint prosthesis

Intervention groups
Injection of 5% and 25% dextrose in the knee joint in 40 patients with mild to moderate knee osteoarthritis in the age range of 45-75 years

Main outcome variables
Scores of WOMAC and KPS questionnaires; clinical and functional status of the joint and persistence of the drug for 6 months after ending the treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190921044831N2**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-29, 1400/08/07**
Update count: **0**

Registration date
2021-10-29, 1400/08/07

Registrant information

Name
Farima Minaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3893 4320

Email address
minaee.farima@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effects of Prolotherapy with Hypertonic Dextrose in Patients with Osteoarthritis of the Knee: A Randomized Clinical Trial

Public title
Effectiveness evaluation of hypertonic dextrose therapy in knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with mild to moderate knee osteoarthritis aged 45-75 years according to Kellgren-Lawrence criteria and rheumatologist approval Absence of rheumatic diseases such as Rheumatoid Arthritis Pain and tenderness of the knee joint resistant to medicine and conservative therapy for 3 months

Exclusion criteria:
Pregnancy Medicine allergy to Oxycodone and Lidocaine 40kg/m2<BMI History of previous prolotherapy Loosening of ligaments and knee joint History of diabetes History of hematologic disease, especially with palpitations History of taking anticoagulants such as Plavix and warfarin History of joint injection in the last 3 months History of inflammatory joint disease and history of knee joint infection People who are candidates for knee surgery with grade 4 based on Kellgren-lawrence History of joint replacement and presence of joint prosthesis

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization based on a random number table

Blinding (investigator's opinion)
Triple blinded

Blinding description
Preparation and allocation of drugs (25% dextrose) and placebo (normal saline 0.9%) were performed by a nurse, therefore, patients in both control and intervention groups. The rheumatologist who was injecting and the data analyzer were blinded to the condition.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Ethics Committee of Mashhad University of Medical Sciences

Street address
Azadi Square, east door of the university campus

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2021-08-29, 1400/06/07

Ethics committee reference number
IR.Mums.Rec.1400.153

Health conditions studied

1

Description of health condition studied
Knee Osteoarthrits

ICD-10 code
M15.0

ICD-10 code description
Primary generalized (osteo)arthritis

Primary outcomes

1

Description
Score of WOMAC questionnaire

Timepoint
4, 8, 12, 16, 20, 24 weeks after injection

Method of measurement
Score of WOMAC questionnaire

Secondary outcomes

1

Description
Clinical and functional status of the joint and persistence of the drug for 6 months after ending the treatment

Timepoint
6 months after ending the treatment

Method of measurement
Questionnaire and clinical assessment

Intervention groups

1

Description

Intervention group: 80 patients with mild to moderate osteoarthritis of the knee aged 75-45 years for whom the diagnosis was made by physical examination and knee AP graphy according to the criterion (grade lawrence-kellgren) by a rheumatologist based on the inclusion criteria. the patients who were referred to the clinic of Ghaem and Imam Reza hospitals and the specialists' office in Mashhad were selected and after filling out the consent form, they entered the study. they were followed up for 24 weeks. The sample selection was done through random numbers and the consort chart. For each patient, first, sufficient explanations are given about the plan and performance of it and also, the benefits of the injection and the possible side effects of it. The consent form and womac and (scale pain knee) Kps are completed and before starting the procedure, an oxycodone 30 mg tablet is prescribed by Farman Shimi Pharmaceutical Company.The syringes were prepared by a nurse who is not aware of the content of Syringes. syringes in the intervention group contained 5% dextrose and 25% dextrose from Samen Pharmaceutical Company (Mashhad-Iran). In supine position and in the knee with flexion of 10 to 15 degrees, intraarticularly by lateral approach method, under sterile conditions, injection of 6 cc of 25% dextrose solution with 2 cc of lidocaine Caspian vial injected with 22 g needle and 20 cc 5% dextrose solution with lidocaine is injected into the tissues and ligaments around it. The injection is given monthly for 3 months. Injectable dextrose in the knee is not a complication and, if present, includes local pain and a small accumulation of fluid in the tissue at the injection site, and rarely rash, urticaria, and itching at the injection site; It is a muscle cramp and paresthesia that all patients are given full explanations about the side effects of the drug so that in case of any of the side effects, they can immediately call the phone number given by the treating physician or, if possible, visit in person to relieve pain symptoms. And swelling of the injection site is given to NSAID patients and if necessary, the NSAID form is given and the patients' follow-up is done at intervals of 4, 8, 12, 16, 20 and 24 weeks after the injection and the KPS and WOMAC questionnaires are filled out. Patients are advised to take acetaminophen as needed for a week and have a relative rest for the first three days. Patients are also advised to avoid analgesic NSAIDs and dietary supplements if possible during treatment. In case of severe need, indicate the number of days and days of drug use in the form of medication delivered to the patient and refrain from physiotherapy during treatment and do not use NSAIDs 48 hours before referral and injection. Clinical status and function of the patient with a questionnaire womac, Kps are checked in person at each visit and in weeks 4, 8, 12, 16, 20 and 24 and patients are given a mobile number and a landline number.

Category

Treatment - Drugs

2

Description

Control group: 80 patients with mild to moderate osteoarthritis of the knee aged 75-45 years for whom the diagnosis was made by physical examination and knee AP graphy according to the criterion (grade lawrence-kellgren) by a rheumatologist based on the inclusion criteria. the patients who were referred to the clinic of Ghaem and Imam Reza hospitals and the specialists' office in Mashhad were selected and after filling out the consent form, they entered the study. they were followed up for 24 weeks. The sample selection was done through random numbers and the consort chart. For each patient, first, sufficient explanations are given about the plan and performance of it and also, the benefits of the injection and the possible side effects of it. The consent form and womac and (scale pain knee) Kps are completed and before starting the procedure, an oxycodone 30 mg tablet is prescribed by Farman Shimi Pharmaceutical Company.The syringes were prepared by a nurse who is not aware of the content of Syringes. The syringes in the control group contained Normal Saline 0.9% Samen Pharmaceutical Company (Mashhad-Iran). In supine position and in the knee with flexion of 10 to 15 degrees, intraarticularly by lateral approach method, under sterile conditions, injection of the present, includes local pain and a small accumulation of fluid in the tissue at the injection site, and rarely rash, urticaria, and itching at the injection site; It is a muscle cramp and paresthesia that all patients are given full explanations about the side effects of the drug so that in case of any of the side effects, they can immediately call the phone number given by the treating physician or, if possible, visit in person to relieve pain symptoms. And swelling of the injection site is given to NSAID patients and if necessary, the NSAID form is given and the patients' follow-up is done at intervals of 4, 8, 12, 16, 20 and 24 weeks after the injection and the KPS and WOMAC questionnaires are filled out. Patients are advised to take acetaminophen as needed for a week and have a relative rest for the first three days. Patients are also advised to avoid analgesic NSAIDs and dietary supplements if possible during treatment. In case of severe need, indicate the number of days and days of drug use in the form of medication delivered to the patient and refrain from physiotherapy during treatment and do not use NSAIDs 48 hours before referral and injection. Clinical status and function of the patient with a questionnaire womac, Kps are checked in person at each visit and in weeks 4, 8, 12, 16, 20 and 24 and patients are given a mobile number and a landline number.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Mashhad

Full name of responsible person

Maasoumeh salari
Street address
Imam Reza Research and Treatment Center, Imam Reza Hospital, Ibn Sina St.
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9137913316
Phone
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Email
imamreza@mshmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaqodi
Street address
Ghorashi Building, Next to Hoveyzeh Cinema, Daneshgah Street
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Province
Razavi Khorasan
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9138813944
Phone
+98 51 3841 1538
Email
vcresraech@mums.ac.i
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Maasoomeh Salari
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Parisa Nourabadi
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minaee.farima@gmail.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
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
How to sample, number of participants, how to group
When the data will become available and for how long
after publishing the Extracted article
To whom data/document is available
Researchers who have evidence of intent to use documentation in new research
Under which criteria data/document could be used
Submitting the code of ethics and the code of approval of the proposal related to the new research requires the documents of this study
From where data/document is obtainable
Scientific responsible for the trial
What processes are involved for a request to access data/document
Sending Email to the author of the article containing the official request and the code of ethics and the code of approval of their proposal, coordination with the ethics committee of Mashhad University, the consent of all project collaborators and finally making the information available to the researcher
Comments