Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Dextrose prolotherapy effects on the Pain of Knee Osteoarthritis: Comparison of Injection in Acupuncture Points versus Non-Acupuncture points

Protocol summary

Study aim

The purpose of this study is to compare the effect of Dextrose prolotherapy on the severity of knee pain in acupuncture points and non-acupuncture points in patients with knee osteoarthritis.

Design

Twenty-six patients with bilateral knee osteoarthritis were selected based on inclusion criteria. Different intervention will be performed on each knee. This study is double blinded, patients and those who study the outcomes of the study are unaware of the grouping and type of intervention.

Settings and conduct

The site of this study is a special clinic of Kurdistan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: patients with knee osteoarthritis, Over 50 years of age, Less than 30 minutes of morning stiffness, Crepitus on active motion, Bony tenderness, Bony enlargement and no palpable warmth of synovium. Exclusion criteria include:Injection of steroid drugs in the last 2 months, Diabetes, Candidate for knee surgery, Previous treatment with dextrose injection, Knee Infections in the last three months, Knee inflammation, Daily opioid Use, History of arthritis, Arthritis after infection, Joint dysplasia, Congenital anomaly, Crystalopathy, Arthritis after injury, Malignancy, Vascular necrosis and bmi more than 30.

Intervention groups

In the first intervention group, 8 ml of dextrose 20% and 2 ml of lidocaine 1% were injected three times at intervals of one week at acupuncture points and in the second intervention group, 8 ml of dextrose 20% and 2 ml of lidocaine 1% were injected three times at intervals of one week at non-acupuncture points.

Main outcome variables

Knee pain severity;morning Stiffness; physical activity

General information

Reason for update

Update trial steps

Acronym

IRCT registration information

IRCT registration number: **IRCT20181114041657N1**
Registration date: **2018-12-08, 1397/09/17**
Registration timing: **prospective**

Last update: **2020-03-13, 1398/12/23**
Update count: **5**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name
Arash Barghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 45 3375 1307
Email address
drarash1979@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-07-06, 1398/04/15

Actual recruitment start date

2019-04-04, 1398/01/15

Actual recruitment end date

2019-07-09, 1398/04/18

Trial completion date

2019-10-02, 1398/07/10

Scientific title
Dextrose prolotherapy effects on the Pain of Knee Osteoarthritis: Comparison of Injection in Acupuncture Points versus Non-Acupuncture points

Public title
The effect of injection of dextrose solution on the severity of knee pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with knee osteoarthritis Over 50 years of age Less than 30 minutes of morning stiffness Crepitus on active motion Bony tenderness Bony enlargement No palpable warmth of synovium

Exclusion criteria:
Injection of steroid drugs in the last 2 months Diabetes Candidate for knee surgery Previous treatment with dextrose injection Knee Infections in the last three months Knee inflammation Daily opioid Use History of arthritis Arthritis after infection Joint dysplasia Congenital anomaly Crystalopathy Arthritis after injury Malignancy Vascular necrosis bmi>30

Age
From **50 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **26**
More than 1 sample in each individual
Number of samples in each individual: **26**
Patients are enrolled in the study, with both knees suffering from osteoarthritis. Different interventions are performed on each knee.
Actual sample size reached: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were selected using randomized blocking method and entered the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and collaborators who evaluate the outcomes of the study are blind to the study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran

City
Sanandaj

Province
Kurdistan

Postal code
66177-13446

Approval date
2018-09-05, 1397/06/14

Ethics committee reference number
IR.MUK.REC.1397.141

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee pain severity

Timepoint
Before the intervention, one month and two month after the last injection

Method of measurement
Using the Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC)

2

Description
Morning Stiffness

Timepoint
Before the intervention, one month and two month after the last injection

Method of measurement
Using the Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC)

3

Description
Physical activity
Timepoint
Before the intervention, one month and two month after the last injection
Method of measurement
Using the Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first intervention group, 8 ml of dextrose 20% and 2 ml of lidocaine 1% were injected three times at intervals of one week at acupuncture points.
Category
Treatment - Drugs

2

Description
Intervention group: In the second intervention group 8 ml of dextrose 20% and 2 ml of lidocaine 1% were injected three times at intervals of one week at non-acupuncture points.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Special Clinic of Kurdistan University of Medical Sciences
Full name of responsible person
Arash Barghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Arash Barghi
Position
Resident of Anesthesiology
Latest degree
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable