

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Crystallopathy 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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Keshavarz St., Special Clinic of Kurdistan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

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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

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Shahrokh Ebnrasooli

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

Anesthesiology

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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