

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of intra articular injection of triamcinolone in comparison with dextrose prolotherapy on pain and function of patients with knee osteoarthritis, single blind clinical trial

Protocol summary

Study aim

Comparison of triamcinolone and dextrose prolotherapy in patients with knee osteoarthritis

Design

Random clinical trial by block random sampling was investigated in two groups

Settings and conduct

Patients in the Physical Medicine and Rehabilitation Department of Mahdiah Hospital affiliated to Shahid Beheshti University of Medical Sciences were evaluated. Descriptions were obtained for informed consent. These patients entered the study with written written consent after full explanation and all patients who met the criteria for entering the project.

Participants/Inclusion and exclusion criteria

Inclusion criteria: arthralgia since the past 3 months; radiologic evidence of articular damage (grade 2,3 of Kellgren-Lawrence scale) based on knee OA criteria of ACR and age between 45-75 years. Exclusion criteria: systemic diseases such as rheumatoid arthritis (RA), any history of intra articular injection, knee surgery or physiotherapy in the last 3 months.

Intervention groups

The first group of patients treated with a single dose of prosthetic dextrose as an intra-articular injection in a combination of 8 cc dextrose 20% 2 cc lidocaine 1% and intra-articular injection at 4 points around the knee (two points above the patella at the medial part) And one point in the articular line of the medial knee and one point in the anterior knee lateral to the head of the fibula) with 12% dextrose by injection of 2.5 cc each point (a combination of 3 cc dextrose 20% and 2 cc lidocaine 1% in syringe 5). CC, of which only 2.5 cc was injected) in the second group of patients treated with a single intramuscular injection of triamcinolone (40 mg) with one cc of lidocaine.

Main outcome variables

Patient pain and performance based on WOMAC and Lequesne questionnaires

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170311033000N4**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Masume Bayat

Name of organization / entity

Shahid beheshti university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

bayat.masyme@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

2019-01-30, 1397/11/10

Actual recruitment end date

2020-01-30, 1398/11/10

Trial completion date

2020-01-30, 1398/11/10

Scientific title

The effect of intra articular injection of triamcinolone in comparison with dextrose prolotherapy on pain and function of patients with knee osteoarthritis, single blind clinical trial

Public title

Comparison of triamcinolone and dextrose prolotherapy in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: arthralgia since the past 3 months; radiologic evidence of articular damage (grade 2,3 of Kellgren-Lawrence scale) based on knee OA criteria of ACR and age between 45-75 years.

Exclusion criteria:

Exclusion criteria: systemic diseases such as rheumatoid arthritis (RA), any history of intra articular injection, knee surgery or physiotherapy in the last 3 months.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **40**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple individual randomization with statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients as participants and the responsible physician as an assessor of the out comes are blinded to the type of injection

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Ethics committee, Shahid Beheshti University of Medical Sciences, Velenjak street, Teheran, Iran

City

Teheran

Province

Tehran

Postal code

1985717443

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.SBMU.NRITLD.REC.1397.555

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code

Gonarthros

ICD-10 code description

M17

Primary outcomes**1****Description**

knee pain

Timepoint

Before intervention, 1 months & 3 months after intervention

Method of measurement

WOMAC questionnaire

2**Description**

Joint Stiffness

Timepoint

Before intervention, 1 months & 3 months after intervention

Method of measurement

WOMAC questionnaire

3**Description**

function

Timepoint

Before intervention, 1 months & 3 months after intervention

Method of measurement

WOMAC questionnaire

4

Description

The maximum distance of walking

Timepoint

Before intervention, 1 months & 3 months after intervention

Method of measurement

Lequesne Index

5

Description

Activity of daily living

Timepoint

Before intervention, 1 months & 3 months after intervention

Method of measurement

Lequesne Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: triamcinolone, knee intraarticular injection, 40 mg 1 time

Category

Treatment - Drugs

2

Description

Intervention group: Single dextrose prolotherapy as an intra-articular injection of a combination of 8 cc dextrose 20% + 2 cc lidocaine 1% and peri-articular injection at 4 points around the knee

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie hospital

Full name of responsible person

Masumeh Bayat

Street address

Mahdieh Hospital, Rajab Nia Street, Shisheh gar Aley, Fadaian Inslam Street, Shosh Squar, Tehran

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

+98 21 5506 2627

Email

mahdiyeh_hospital@sbmu.ac.ir

Web page address

<http://old.sbmu.ac.ir/SiteDirectory/MahdieHospital>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masumeh Bayat

Street address

Mahdieh Hospital, Rajab nia Street, shisheh gar alley, Fadaian Inslam Street, Shosh Squar, Tehran

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

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Email

mahdiyeh_hospital@sbmu.ac.ir

Web page address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Modabberi

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Mahdieh Hospital, Tehran
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
0098113204024
Fax
+98 21 5506 2627
Email
mohsen_modabberi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masumeh Bayat
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Mahdieh Hospital, Tehran
City
tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Fax
Email

bayat.masyme@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohsen Modabberi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Tehran, Tajrish square, Fanakhosro Ave Plaque 28
اخی
City
Tehran
Province
Tehran
Postal code
1989814133
Phone
0098113204024
Email
mohsen_modabberi@yahoo.com

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
There is no further information
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