Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Mahdieh 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 intera 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)

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+98 21 2273 1112

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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 intera 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 size
Target 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 committe,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
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Sponsors / Funding sources

1

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Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masumeh Bayat
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Mahdieh Hospital, Rajab nia Street, shisheh gar alley, Fadaian Inslam Street, Shosh Squar, Tehran
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Web page address
http://old.sbmu.ac.ir/SiteDirectory/MahdieHospital
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
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Medical doctor
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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