

# 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 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 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 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

Mahdiah 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

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##### Email

mahdiah\_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

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

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mahdiah\_hospital@sbmu.ac.ir

##### 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  
**Latest degree**  
Medical doctor  
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Physical Medicine  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences  
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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