

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Periarticular hypertonic dextrose Vs intraarticular hyaluronic acid injections; Comparison of two minimally invasive Techniques in the treatment of symptomatic knee osteoarthritis

#### Protocol summary

##### Study aim

Comparison of Dextrose periarticular Injection versus Hyaluronic Acid Intraarticular Injection in the treatment of pain of knee osteoarthritis

##### Design

In a double-blind randomized clinical trial, 104 patients with knee pain for at least 3 months (who have not responded adequately to conservative treatment) and in accordance with the inclusion and exclusion criteria, are enrolled. Patients are randomly divided to two groups. Before the main injections, lidocaine 2% used as local anesthetic. For the HA group, 2.5 mL of hyaluronic acid is injected intraarticular. HD group, is received 10 ml of 12.5% hypertonic dextrose through four points around the knee. All injections are done by a 23-G needle subcutaneously under ultrasound guidance. The injections are done, three times within two weeks, at days 0, 7 and 14. All patients are evaluated using the VAS (0-10), WOMAC (0-100) criteria before and 3 months after the last injection. At the first injection time and Three months later, the pain intensity and the WOMAC scores are obtained for all patients and compared intra and between groups.

##### Settings and conduct

In a double-blind randomized clinical trial, 104 patients with knee pain for at least 3 months (who have not responded adequately to conservative treatment) and in accordance with the inclusion and exclusion criteria, are enrolled. Patients are randomly divided to two groups. The injections are done, three times within two weeks, at days 0, 7 and 14. All patients are evaluated using the VAS (0-10), WOMAC (0-100) criteria before and 3 months after the last injection. At the first injection time and Three months later, the pain intensity and the WOMAC scores are obtained for all patients and compared intra and between groups. All analgesics were discontinued 48 hours before the procedure and for up to 2 weeks after

the procedure (except acetaminophen). Physician injecting drug and the one evaluating patients in follow-up is different and is blind to patients group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic osteoarthritis; grade 2 or higher of OA in radiology; age over 50 years; morning stiffness less than 30 minutes; 3 month unresponsiveness to conservative therapy Exclusion criteria: severe underlying diseases like diabetes and/or hypothyroidism; immune suppression or deficiency; serious local infectious or inflammatory knee disease; anticoagulant drug history during three last months; history of corticosteroid therapy in past year; history of prolotherapy in past year; history of intraarticular injection in past year; indication for surgical arthroplasty

##### Intervention groups

For the HA group, 2.5 mL of hyaluronic acid is injected intraarticular via the inferomedial of patella. The HD group, is received 10 ml of 12.5% hypertonic dextrose through four points injection, two points at suprolateral of patella, one point at medial knee joint line and another remained point is at anterior of fibula head, via fan wise technique, 2.5 cc for each point.

##### Main outcome variables

pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130518013364N6**

Registration date: **2018-02-20, 1396/12/01**

Registration timing: **retrospective**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

##### Registration date

2018-02-20, 1396/12/01

## Registrant information

### Name

Mehrdad Taheri

### Name of organization / entity

Shahid Beheshti University of Medical Science

### Country

Iran (Islamic Republic of)

### Phone

+98 21 7756 7840

### Email address

m.taheri@sbmu.ac.ir

## Recruitment status

### Recruitment complete

## Funding source

## Expected recruitment start date

2016-02-09, 1394/11/20

## Expected recruitment end date

2017-03-19, 1395/12/29

## Actual recruitment start date

2016-02-14, 1394/11/25

## Actual recruitment end date

2017-04-30, 1396/02/10

## Trial completion date

empty

## Scientific title

Periarticular hypertonic dextrose Vs intraarticular hyaluronic acid injections; Comparison of two minimally invasive Techniques in the treatment of symptomatic knee osteoarthritis

## Public title

Comparison of dextrose and hyaluronic acid in the treatment of pain in osteoarthritis of the knee

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with chronic osteoarthritis Grade 2 or higher of OA in radiology Age over 50 years Morning stiffness less than 30 minutes 3 month unresponsiveness to conservative therapy

### Exclusion criteria:

Severe underlying diseases like diabetes and/or hypothyroidism, immune suppression or deficiency Serious local infectious or inflammatory knee disease Anticoagulant drug history during three last months History of corticosteroid therapy in past year History of prolotherapy in past year History of intraarticular injection in past year Indication for surgical arthroplasty

## Age

From 50 years old to 75 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: 104

Actual sample size reached: 104

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are allocated to two group, using randomized numbers table

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The physicians who inject the drug solutions and the ones who evaluate the patients in follow-up visits, are different and are blind to the subject.

## 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

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

#### Approval date

2016-02-07, 1394/11/18

#### Ethics committee reference number

IR.SBMU.RAM.REC.1394.528

## Health conditions studied

### 1

#### Description of health condition studied

Gonarthrosis [arthrosis of knee]

#### ICD-10 code

M17.0

#### ICD-10 code description

Primary gonarthrosis, bilateral

## Primary outcomes

### 1

#### Description

Pain  
**Timepoint**  
3 months  
**Method of measurement**  
VAS

## 2

**Description**  
WOMAC Index  
**Timepoint**  
3 months  
**Method of measurement**  
The Western Ontario and McMaster Universities  
Osteoarthritis Index (WOMAC)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
Intervention group: For the HA group, 2.5 mL of hyaluronic acid is injected intraarticular via the inferomedial of patella.  
**Category**  
Treatment - Other

### 2

**Description**  
Intervention group: The HD group, is received 10 ml of 12.5% hypertonic dextrose through four points injection, two points at suprolateral of patella, one point at medial knee joint line and another remained point is at anterior of fibula head, via fan wise technique, 2.5 cc for each point.  
**Category**  
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Imam Hossein Hospital's pain clinic  
**Full name of responsible person**  
Mehrddad Taheri  
**Street address**  
Shahid Madani street  
**City**  
Tehran  
**Province**  
Tehran  
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1617763141  
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## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Vice Chancellor for Research and Technology of Shahid Beheshti University Of Medical Sciences  
**Street address**  
Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway  
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Tehran  
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1985717434  
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+98 21 2243 9951  
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mpd@sbmu.ac.ir  
**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**  
Mehrddad Taheri  
**Position**  
Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
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Shahid Madani street-Imam Hossein Hospital  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Latest degree**

Subspecialist  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Information on the initial and main implications

### When the data will become available and for how long

Since 2018

### To whom data/document is available

Researchers working in academic institutions

### Under which criteria data/document could be used

There are no special conditions

### From where data/document is obtainable

Mehrdad Taheri taheri.1352@yahoo.com

### What processes are involved for a request to access data/document

Send a request by e-mail

### Comments