

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of long term efficacy of dextrose prolotherapy with hyalgan in knee Osteoarthritis

#### Protocol summary

##### Summary

After The accurate diagnosis of osteoarthritis (clinical and radiographic) , And evaluation of patient inclusion & exclusion criteria for the study, Details of treatment is described and the patient's written consent is obtained. Other drug treatments (NSAID, corticosteroids and other anti-inflammatory drugs) and non pharmacological (knee physiotherapy modalities are included, TENS, laser, etc.) will be discontinued 48 hours before the start of the intervention. Then initial knee x-ray is taken. And according to radiographic criteria, grading is done and initial patient questionnaire is completed. Then knee joint range of motion (ROM) measured by Goniometr & Medial and lateral joint line tenderness is reviewed & Pain intensity on VAS (state separation as the rest, walking, sitting, etc.) And according to the WOMAC questionnaire is assessed. The grouping is done, the other person does the first Hyalgan injections and hypertonic dextrose or 20% .A total of 3 patients were injected into the knee joint to be considered. Injections in patients treated with Hyalgan, at intervals of one week (vials 2 ml prepared hyaluronic acid) and in patients treated Prolotherapy three injections at intervals of one month (compound 9 ml of glucose 20% with 1 cc of lidocaine 2% in a syringe 10 cc) is done. After injection, it is recommended that patients have a relative rest for 48 hours, it increases the duration of maintaining and enhancing the response to treatment. for sterility , sterile gloves & sterile infusion sets are used. Before each injection, patients were reassessed for pain (VAS and a questionnaire based on numerical criteria WOMAC), range of motion, tenderness of the joint line (medial and lateral) and injection complications (infection, Hemartrosis,...) are checked. Patients can be followed during the course of the pain, take acetaminophen 325, But the 12 hours prior to treatment to follow, do not use acetaminophen. After treatment protocol (three injections and in each stage of the assessment), range of motion, pain and joint line

tenderness is measured.

#### General information

##### Acronym

Comparison of prolotherapy with hyalgan

##### IRCT registration information

IRCT registration number: **IRCT2013031712831N1**

Registration date: **2013-08-28, 1392/06/06**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-28, 1392/06/06

##### Registrant information

###### Name

Masoumeh Bahrami Asl

###### Name of organization / entity

Army University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8833 7915

###### Email address

masoomehbahrami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Army University of Medical Sciences

##### Expected recruitment start date

2013-06-11, 1392/03/21

##### Expected recruitment end date

2014-02-19, 1392/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of long term efficacy of dextrose prolotherapy with hyalgan in knee Osteoarthritis

**Public title**  
Comparison of long term efficacy of dextrose prolotherapy with hyalgan in knee Osteoarthritis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: age more than 50 years old; cripitation or morning stiffness less than 30 min & radiologic criteria of OA. Exclusion criteria: diabetes mellitus; other joint disease ( RA,...); surgery in knee; fx history;recent corticosteroid injection; immunosuppression and massive knee effusion.

**Age**  
From **50 years** old to **90 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **110**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
army university of medical science

**Street address**  
Imam reza( 501) hospital - Etemad Zadeh street-  
Fatem

**City**  
tehran

**Postal code**

**Approval date**  
2013-06-11, 1392/03/21

**Ethics committee reference number**

9204

## Health conditions studied

### 1

#### Description of health condition studied

knee OA

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

pain severity (pain score)

#### Timepoint

1 week, 1 month, 3 month , 8 month and 12 month

#### Method of measurement

VAS ruller

### 2

#### Description

knee joint range of motion

#### Timepoint

1 week, 1 month, 3 month , 8 month and 12 month

#### Method of measurement

goniometr

### 3

#### Description

quality of life

#### Timepoint

1 week, 1 month, 3 month and 8 month

#### Method of measurement

WOMAC questionnaire

## Secondary outcomes

### 1

#### Description

infection

#### Timepoint

1 week, 1 month, 3 month , 8 month and 12 month

#### Method of measurement

physical exam

## Intervention groups

### 1

#### Description

intervention:in prolotherapy group we use ,9cc of 20% dextrose + 1cc lidocaine in strill condition & in knee joint space

#### Category

Treatment - Drugs

## 2

### Description

control: we use prepared vial of 2 cc hyalgan in strill condition & in knee joint space

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital (501)

##### Full name of responsible person

Dr. Masoumeh Bahrami Asl

##### Street address

Imam reza( 501) hospital - Etemad Zadeh street-Fatem

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Army University of Medical Sciences

##### Full name of responsible person

Dr Zahra Reza Soltani

##### Street address

Imam reza( 501) hospital - Etemad Zadeh street-Fatem

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Army University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Army University of Medical Sciences

#### Full name of responsible person

Dr Masoumeh Bahrami Asl

#### Position

Assistant of physical medicine and rehabilitation

#### Other areas of specialty/work

#### Street address

Imam reza( 501) hospital - Etemad Zadeh street-Fatem

#### City

Tehran

#### Postal code

#### Phone

+98 21 8833 7915

#### Fax

#### Email

masoomehbahrami@yahoo.com;

m.bahrami.asl@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Army University of Medical Sciences

#### Full name of responsible person

Dr. Masoumeh Bahrami Asl

#### Position

Assistant of physical medicine & rehabilitation

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Army University of Medical Sciences

#### Full name of responsible person

Dr Masoumeh Bahrami Asl

#### Position

assistant of physical medicine & rehaabilitation

#### Other areas of specialty/work

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+98 21 8833 7915

#### Fax

**Email**

masoomehbahrami@yahoo.comm.bahrami.asl@gmail  
.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*