

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Hyaluronic Acid Compared with Corticosteroid Injections for the Treatment of Osteoarthritis of the knee

#### Protocol summary

##### Summary

This randomized, double blind, parallel study was conducted with 140 knee OA patient to compare the Therapeutic effects of corticosteroids and hyaluronic acid. Patients will visit by a physician . after they signed informed consent they will choose. individuals randomly divided into two groups. Intensity of pain will assess by Visual analogue scale and Western Ontario McMaster University Osteoarthritis questionnaire. The treatment consisted of one IA injections of HA or one injections of CS and the follow-up visits were scheduled at 1 months, 2 months, and 3 months Qualified patients were men and women from 45 years to 80 years of age suffering from knee OA for more than 3 months, with radiographic. Main exclusion criteria was The use of NSAIDs in 2 days prior to injection. Patients and investigators were blinded in this study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015031421460N1**

Registration date: **2015-08-01, 1394/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-01, 1394/05/10

##### Registrant information

##### Name

Tahereh Gholami

##### Name of organization / entity

Fasa University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5335 7091

##### Email address

gholami@fums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Fasa University of Medical Sciences

##### Expected recruitment start date

2015-05-05, 1394/02/15

##### Expected recruitment end date

2015-06-05, 1394/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Hyaluronic Acid Compared with Corticosteroid Injections for the Treatment of Osteoarthritis of the knee

##### Public title

Hyaluronic Acid Compared with Corticosteroid Injections for the Treatment of Osteoarthritis of the knee

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Qualified patients were men and women from 45 years to 80 years of age suffering from knee OA for more than 3 months, with radiographic. Main exclusion criteria were a history or presence of trauma or surgery or cancer or malignant tumors, infections and sores on the target knee, History of vasovagal shock , The use of NSAIDs in 2 days prior to injection, Any receiving corticosteroids injection in the knee in the last 6 months , Pregnancy and lactation

##### Age

From **48 years** old to **13 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **140**

**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**

Ethics Committee of Fasa University of Medical Sciences

**Street address**

Fasa University of Medical Sciences, Ebne Sina square, Fasa, Fars

**City**

Fasa

**Postal code**

**Approval date**

2014-12-02, 1393/09/11

**Ethics committee reference number**

e- 9306

## Health conditions studied

1

**Description of health condition studied**

Knee Osteoarthritis

**ICD-10 code**

M17- M18-

**ICD-10 code description**

Gonarthrosis [arthrosis of knee]

## Primary outcomes

1

**Description**

pain

**Timepoint**

before intervention- one- two- three months after intervention

**Method of measurement**

Visual analogue scale and questionnaire

## Secondary outcomes

1

**Description**

Physical function

**Timepoint**

before and after intervention

**Method of measurement**

questionnaire and interview with patients

## Intervention groups

1

**Description**

Patients participating in the study will be divided into two groups of 70 people. One group will take 40 mg Depomedrol corticosteroid injection in the space between the knee joint by an orthopedic physician. And second group will take hyaluronic acid (Hyalgan) in 2 ml vials to the space between the knee joint by an orthopedic physician.

**Category**

Treatment - Drugs

2

**Description**

intervention group: hyaluronic acid (Hyalgan) in 2 ml vials to the space between the knee joint by an orthopedic physician

**Category**

Treatment - Drugs

3

**Description**

control group: this group will take 40 mg Depomedrol corticosteroid injection in the space between the knee joint by an orthopedic physician

**Category**

Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Hamzeh hospital/ Fasa University of Medical Sciences

**Full name of responsible person**

Tahereh Gholami

**Street address**

Fasa University of Medical Sciences

**City**

## Sponsors / Funding sources

**1**

### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Fasa University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Bahramali

**Street address**

Fasa University of Medical Sciences, Ebne Sina square, Fasa, Fars

**City**

Fasa

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research of Fasa 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**

Fasa University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Askari

**Position**

Orthopedics/ Faculty

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Tahereh Gholami

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ergonomics- faculty

**Other areas of specialty/work**

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## 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*

