

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 2026

### Comparison of the outcome of Platelet-rich plasma and hyaluronic acid injections in the treatment of degenerative joint disease of knee

#### Protocol summary

##### Study aim

The aim of the present study is to compare the efficacy of platelet-rich plasma and hyaluronic acid injections in the treatment of knee osteoarthritis.

##### Design

The patients are assigned into three groups of at least 27 people. The assignment into the three groups of single PRP injection, double PRP injections and hyaluronic acid is conducted by random allocation.

##### Settings and conduct

This single-blinded controlled trial, in which the researcher is blinded, is performed on the patients aged 40-80 years old with osteoarthritis who are referred to Shahid Beheshti Hospital in Babol.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria are as follows: Patients with diagnosis of bilateral knee osteoarthritis based on American college of Rheumatology, morning stiffness lasting less than 30 minutes, radiographic evidence of osteoarthritis, and symptoms lasting at least 3 months.

##### Intervention groups

Three groups: Single PRP injection, double PRP injections, hyaluronic acid

##### Main outcome variables

Primary objective: Change in Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain sub-scale.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180129038548N1**

Registration date: **2018-08-11, 1397/05/20**

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

Last update: **2018-08-11, 1397/05/20**

Update count: **0**

##### Registration date

2018-08-11, 1397/05/20

##### Registrant information

###### Name

Seyed Mokhtar Esmaeilnezhad Ganji

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3219 9936

###### Email address

smsganji@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-04-26, 1397/02/06

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the outcome of Platelet-rich plasma and hyaluronic acid injections in the treatment of degenerative joint disease of knee

##### Public title

Comparison of the Platelet-rich plasma and hyaluronic acid injections in treatment of knee osteoarthritis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with diagnosis of bilateral knee osteoarthritis based on American college of Rheumatology. Morning stiffness lasting less than 30 minutes Radiographic evidence of osteoarthritis Symptoms lasting at least 3 months

**Exclusion criteria:**

Other knee joint diseases, like rheumatoid arthritis and gout. Intra-articular knee joint corticosteroid injection over the past two weeks

**Age**

From **40 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **81**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients are randomly divided by using a computer-generated random number list. The subjects are assigned into different groups by random allocation. Allocation concealment is obtained by maintaining the randomization list by study statistician.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, the researcher is blinded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

**Street address**

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran.

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶-۴۷۷۴۵

**Approval date**

2018-07-08, 1397/04/17

**Ethics committee reference number**

IR.MUBABOL.HRI.REC.1397.082

## Health conditions studied

### 1

**Description of health condition studied**

Osteoarthritis

**ICD-10 code**

M15.9

**ICD-10 code description**

Polyosteoarthritis, unspecified

## Primary outcomes

### 1

**Description**

Change in Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain sub-scale.

**Timepoint**

Weeks 4, 8 and 12 of treatment.

**Method of measurement**

Based on Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) and Visual Analogue Scale (VAS).

## Secondary outcomes

### 1

**Description**

Change in global Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC).

**Timepoint**

Weeks 4, 8 and 12 of treatment.

**Method of measurement**

Based on Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC).

## Intervention groups

### 1

**Description**

Intervention group: Single PRP Injection

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: Double PRP Injection

**Category**

Treatment - Drugs

### 3

**Description**

Control group: Hyalgan

**Category**

Treatment - Drugs

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

Seyed Mokhtar Esmailnejad Ganji

**Street address**Shahid Beheshti Hospital, Shahid Sargord Ghasemi  
Street, Babol, Mazandaran, Iran.**City**

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4716681451

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beheshti@mubabol.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**Vice Chancellor for Research and Technology of Babol  
University of Medical Sciences**Full name of responsible person**

Dr. Reza Ghadimi

**Street address**Babol University of Medical Sciences, Ganjafrroz  
Street, Babol, Mazandaran, Iran.**City**

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**Phone**

+98 11 3219 9592

**Email**

info@mubabol.ac.ir

**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 and Technology of Babol  
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**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Mokhtar Esmailnejad Ganji

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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## Person responsible for updating data

smsganji@yahoo.com

### Contact

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Babol University of Medical Sciences

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**Email**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available