

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)

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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 centers1**Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Seyed Mokhtar Esmailnejad Ganji

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Shahid Beheshti Hospital, Shahid Sargord Ghasemi Street, Babol, Mazandaran, Iran.

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Sponsors / Funding sources1**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

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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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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