

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of functional improvement and quality of life in knee osteoarthritis after treatment of PRP (platelet rich plasma) and exercise: a randomized controlled trial

#### Protocol summary

##### Summary

Goal: comparison of functional improvement and quality of life in knee osteoarthritis after treatment of PRP (platelet rich plasma) and exercise. Osteoarthritis (OA) is a highly prevalent, chronic, degenerative condition that generates a high expense. Alternative and co-adjuvant therapies to improve the quality of life and physical function of patients are currently being sought. Methods: A total of 66 patients with knee OA were treated with PRP (plasma rich in growth factors), and exercise in 2 groups (intervention and control) with OA of the knee (Outer bridge grades I-IV) and symptoms of >3 months duration met the inclusion criteria (age <75yr, history without of hematologic disorder and diabetes ...) and. 2 intra-articular injections of autologous PRP were administered at 4-week intervals in outpatient surgery and knee exercise is taught to both intervention and control groups. Participants were asked to fill out a questionnaire with personal data and the following assessment instruments: SF-36, WOMAC Index, before the injection of PRP and 6 months after injection or exercise.

#### General information

##### Acronym

PRP =platelet rich plasma

##### IRCT registration information

IRCT registration number: **IRCT201110117770N1**

Registration date: **2013-01-18, 1391/10/29**

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

Last update:

Update count: **0**

##### Registration date

2013-01-18, 1391/10/29

#### Registrant information

##### Name

Marzieh Babaee

##### Name of organization / entity

Physical medicine and rehabilitation department,  
Shahid Beheshti university of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2273 1112

##### Email address

marzieh.babaee@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research of Shahid Beheshti  
University of Medical Sciences

#### Expected recruitment start date

2012-02-20, 1390/12/01

#### Expected recruitment end date

2013-02-19, 1391/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of functional improvement and quality of life in knee osteoarthritis after treatment of PRP (platelet rich plasma) and exercise: a randomized controlled trial

#### Public title

Effectiveness of PRP in treatment of Knee degenerative disorder

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: history of chronic (at least 3months) pain or swelling of the knee and imaging findings (X-ray or MRI) of degenerative changes of the joint according of American college of Rheumatology. Exclusion criteria: systemic disorders such as diabetes, rheumatoid arthritis, major axial deviation (varum 20 degree, valgum 20 degree), hematological diseases (coagulopathy), severe cardiovascular diseases, infections, immunodepression, patients in therapy with anticoagulants or antiaggregants, the use of NSAIDs in the 2 days before blood donation and patients with Hb values of 12 and platelet values of 150,000/mmc; Pregnancy; breast feeding; vasovagal shock; severe trauma; injection of corticosteroid in knee joint since 2 weeks ago.

### Age

To 75 years old

### Gender

Both

### Phase

3

### Groups that have been masked

No information

### Sample size

Target sample size: 66

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committe of Shahid beheshti University of Medical sciences

##### Street address

Shahid beheshti University of Medical sciences,Velenjak

##### City

Tehran

##### Postal code

#### Approval date

2012-10-28, 1391/08/07

#### Ethics committee reference number

124

## Health conditions studied

### 1

#### Description of health condition studied

Knee osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Gonarthrosis [arthrosis of knee]

## Primary outcomes

### 1

#### Description

function

#### Timepoint

6 months

#### Method of measurement

WOMAC Questianir

### 2

#### Description

quality of life

#### Timepoint

6 months

#### Method of measurement

SF36 questinair

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

5 cc of PRP injection in 4 weeks interval and knee isometric exercise (4 types) 3 times in day, 10 times every exercise

#### Category

Treatment - Drugs

### 2

#### Description

knee isometric exercise (4 types) 3 times in day, 10 times every exercise

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Modares and Shohadaye Tajrish Hospital

##### Full name of responsible person

**Street address**

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti university of Medical sciences

**Full name of responsible person**

Vice chancellor for research, Dr. Rahmati Roodsari

**Street address**

Shahid Beheshti university of Medical sciences ,  
Kodakyar alley,Velenjak

**City**

Tehran

**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**

*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**

Physical medicine and Rehabilitation department of  
Shahid Beheshti university of medical sciences

**Full name of responsible person**

Marzieh Babaee

**Position**

resident

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

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**Fax**

**Email**

**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*