Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of effects of intra - articular injection of Platelet Rich Plasma (PRP), Plasma Rich in Growth Factor (PRGF), Hyaluronic Acid (HA), and Ozone Gas on pain, stiffness, and function of patients with knee osteoarthritis

Protocol summary

Summary

120 patients with knee osteoarthritis with a specific age range and duration of symptoms more than 3 months and having Inclusion criteria, are included in the study. Evidence and method of injection of PRGF, Ozone, PRP and HA, as well as the potential benefits and complications of the study are presented by a physiatrist. Patients are screened at the first visit, including history, physical examinations, laboratory requests (CBC, ESR, CRP) and knee AP and Lateral x-Ray view in standing position and patient medications. Then patients are randomized to four groups receiving PRGF, Ozone, PRP, and HA. For each group appropriate exercise therapy is prescribed . At the beginning of the study, and in order to measure the outcome of the patients in the 6th and 12th months after the completion of the injections, WOMAC and VAS questionnaires were used to assess joint stiffness, functional limitation and pain intensity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082013442N17**
Registration date: **2017-11-11, 1396/08/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-11, 1396/08/20

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

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Recruitment status

Recruitment complete

Funding source

Physical Medicine and Rehabilitation Research Center of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effects of intra - articular injection of Platelet Rich Plasma (PRP), Plasma Rich in Growth Factor (PRGF), Hyaluronic Acid (HA), and Ozone Gas on pain, stiffness, and function of patients with knee osteoarthritis

Public title

The comparison of effects of different intra-articular injections on the symptoms of patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with knee osteoarthritis according to the American College of Rheumatology criteria aged between 50-70 years and with symptoms that have been diagnosed for more than 3 months and radiologic evidence of articular damage (grade 1-4 of Kellgren-Lawrence scale) Exclusion criteria: 1- systemic diseases such as diabetes mellitus, Immunodeficiency and collagen vascular disorders 2- history or presence of cancer or malignant disorders 3- any infection and active wound of the knee 4-presence of autoimmune diseases and platelet disorders 5- use of NSAIDs 2 days before injection 6- treatment with anticoagulant and anti-platelet medications 10 days before injection 7-history of knee articular injections of corticosteroids 3 weeks or use of systemic corticosteroids 2 weeks before injections 8-hemoglobin measures of less than 12 g/dl and platelet counts of less than 150,000 per micro liter 9- recent history of severe trauma to the knee 10-age less than 40 or over 75 years 11- history of vasovagal shock 12-pregnancy and breastfeeding 13- genu valgum/varum greater than 20 degrees 14-Allergy to chicken or egg protein or hypersensitivity to hyaluronate 15-patients treated with ACE inhibitors. 16-G6PD deficiency

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random table number is used to randomize. This is a single blind study and patients are not aware of the type of injected drug.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Ave., Yaman St., Shahid Chamran highway

City

Tehran

Postal code

1985717443

Approval date

2017-02-21, 1395/12/03

Ethics committee reference number

IR.SBMU.MSP.REC.1396.230

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

knee pain

Timepoint

before intervention,6 months & 12months after intervention

Method of measurement

changes of WOMAC and VAS questionnaires scores

2

Description

Joint Stiffness

Timepoint

before intervention,6 months & 12months after intervention

Method of measurement

change of WOMAC questionnaire scores

3

Description

function

Timepoint

before intervention,6 months & 12months after intervention

Method of measurement

change of WOMAC questionnaire scores

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: plasma rich in growth factor, knee intraarticular injection, 4 to 6 milliliter, 2 times, 3 weeks interval
Category
Treatment - Drugs

2

Description
Intervention group 2: platelet rich in plasma , knee intraarticular injection, 4 to 6 milliliter, 2 times, 3 weeks interval
Category
Treatment - Drugs

3

Description
Intervention group 3: Hyaluronic acid (500,000 to 730000 Daltons),3times, weekly
Category
Treatment - Drugs

4

Description
Intervention group 4: Ozone Gas, knee intraarticuar injection,10 ml with a concentration of 30 µg per cc 3 times, weekly
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Seyed Ahmad Raeissadat
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
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Tehran, Saadat Abad, Kaj Square, Shahid Modarres Hospital
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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, 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

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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

Data Dictionary

empty