

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The comparison of platelet rich plasma injection versus exercise therapy with TENS modality in improvement of sign and symptoms among patients with osteoarthritis of knee, a randomized clinical trial in Rasoul Akram hospital

Protocol summary

Summary

patients who suffer from knee osteoarthritis according to diagnostic clinical findings and radiological criteria will be divided to two groups randomly. All patients fill consent forms before enter the study and after that all of them fill VAS and KOOS evaluating forms and do treadmill test. In case group the patients will be injected by PRP two times in 4 weeks and we will use TENS and exercise therapy for control group and 4 and 8 weeks after beginning of the study; all patients will be reevaluated by VAS and KOOS and treadmill test. Finally two groups will be compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110611382N1**

Registration date: **2012-12-04, 1391/09/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-04, 1391/09/14

Registrant information

Name

Hooman Angoorani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-12-01, 1391/09/11

Expected recruitment end date

2013-11-30, 1392/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of platelet rich plasma injection versus exercise therapy with TENS modality in improvement of sign and symptoms among patients with osteoarthritis of knee, a randomized clinical trial in Rasoul Akram hospital

Public title

Effect of platelet rich plasma on treatment of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male and female with knee pain in stage 1-3 Kellgren Lawrence; no history of intra-knee injection of steroids within last three months; no history of spinal stenosis; no history of blood disorder and consumption of anticoagulative drugs. Exclusion criteria: Inability for physical activity; patient's request to leave study; intra-knee injection of steroids during study; suffering debilitating diseases during study that interfere

with patient's physical activity; applying pacemaker due to physical condition during the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 54

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**

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences,
poursina.keshavarz blv.

City

Tehran

Postal code**Approval date**

2012-07-11, 1391/04/21

Ethics committee reference number

130/666/91/3

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Primary gonarthrosis

Primary outcomes**1****Description**

knee pain

Timepoint

before the intervention then 4 and 8 weeks after the beginning of the intervention

Method of measurement

vas form

2**Description**

morning stiffness

Timepoint

before the intervention then 4 and 8 weeks after the beginning of the intervention

Method of measurement

standardized koos questionnaire

3**Description**

ROM improvement

Timepoint

before the intervention then 4 and 8 weeks after the beginning of the intervention

Method of measurement

standardized koos questionnaire

4**Description**

intolerable pain inception time in treadmill walking test

Timepoint

before the intervention then 4 and 8 weeks after the beginning of the intervention

Method of measurement

walking on treadmill

Secondary outcomes

empty

Intervention groups**1****Description**

intraknee injection of platelet rich plasma

Category

Treatment - Other

2**Description**

Trans Epidermal Nerve Stimulation(TENS) Exercise Therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Dr. Hooman Angoorani

Street address

Sports medicine assessment clinic, 8 floor, Rasoul akram hospital, Niayesh st, Satarkhan st, Tehran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research sector of Tehran University Of Medical Sciences

Full name of responsible person

Dr. Akbar Footoohi

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research part, poursina, Tehran University Of Medical Sciences

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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

Research sector of Tehran 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**

Rasoul Akram Hospital

Full name of responsible person

Dr.Omid Marjomaki

Position

resident of sports medicine

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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