

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of intra-articular injection of hydrolyzed type 1 collagen, platelet-rich plasma and hyaluronic acid on pain, stiffness and performance of patients with knee osteoarthritis

Protocol summary

Study aim

The purpose of this study is comparing the effectiveness of intra-articular injection of hyaluronic acid, hydrolyzed collagen, and platelet-rich plasma in reducing pain, improving function, and the level of satisfaction with treatment of knee osteoarthritis.

Design

A controlled, parallel-group, double blind, randomized, phase 3 clinical trial on 120 patients. Random allocation software is used for randomization.

Settings and conduct

Subjects, interventionist, outcome assessor, statistician and the researcher are all blind to treatment groups allocation; using pre-filled syringes and sealed envelopes. Subjects will be randomly allocated in 3 groups. The study will take place in Modarres hospital, Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 40 to 70 years with a BMI between 18 and 30, based on history and physical examination, knee osteoarthritis is diagnosed and confirmed by using knee x-rays (Kellgren-Lawrence grade 2-3) and the duration of symptoms is more than 3 months. Exclusion criteria : History of uncontrolled diabetes, immunodeficiency, and collagen disorders; Use of NSAIDs within 2 days before injection; Pregnancy or breastfeeding; Geneva valgum/varum more than 20 degrees and Clinical or para-clinical symptoms in favor of spinal canal narrowing, neuropathy, active lumbar radiculopathy

Intervention groups

Intervention group 1: includes 40 patients who are treated with CHondroGrid made of low molecular weight hydrolyzed collagen. Intervention group 2: Includes 40 patients who are treated with PRP in three injections with two-week intervals intra-articularly. Intervention group 3: Includes 40 patients who are treated with HA injection in

three injections with two weeks intervals intra-articularly

Main outcome variables

Assessment of knee pain and stiffness, assessment of patient's function in daily tasks and degree of patient's satisfaction.

General information

Reason for update

With the aim of more accurately and completely determining the exclusion criteria and clarifying the title of the research project and specifying the brand and characteristics of hyaluronic acid used in this research project, an update was made.

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N34**
Registration date: **2023-09-23, 1402/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-08, 1402/11/19**

Update count: **1**

Registration date

2023-09-23, 1402/07/01

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intra-articular injection of hydrolyzed type 1 collagen, platelet-rich plasma and hyaluronic acid on pain, stiffness and performance of patients with knee osteoarthritis

Public title

Comparison of intra-articular injection of hydrolyzed type 1 collagen, platelet-rich plasma and hyaluronic acid on pain, stiffness and performance of patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged 40 to 70 years who are diagnosed with knee osteoarthritis based on history and physical examination. Duration of symptoms is more than 3 months. Confirmation of diagnosis using knee x-ray (Kellgren-Lawrence grade 2-3) The patient's BMI should be between 18 and 30. Willingness of the patient to participate in the study

Exclusion criteria:

History of immunodeficiency and collagen disorders and uncontrolled diabetes History or presence of malignant disorders, infection or active wound in the knee area Recent history of severe knee injury Autoimmune and platelet disorders Treatment with anticoagulant and antiplatelet drugs within 10 days before injection Use of NSAIDs within 2 days before injection History of intramuscular injection or oral use of systemic corticosteroids 2 weeks before injection History of any intra-articular injection of the knee during the last 6 months Hemoglobin less than 11 g/dL Platelet count less than 150,000/ml History of vasovagal shock Pregnancy or breastfeeding Geneva valgum/varum more than 20 degrees Hypersensitivity to hyaluronate Allergy to bovine proteins, poultry products, eggs and collagen Hemarthrosis, erythema and psoriatic lesions Clinical or para-clinical symptoms in favor of spinal canal narrowing, neuropathy or active lumbar radiculopathy

Age

From 40 years old to 70 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

in this clinical trial study, 60 patients with a diagnosis of frozen shoulder will be included in the study randomly .For random allocation of individuals in the study groups, the method of random allocation with block method (Block Randomization) will be used In this method, blocks with size of six (including two people in in each of the three groups) with a ratio of 1:1:1 will be used. Random Allocation software will be used to generate random sequences. For concealment, the random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified with three types of cards which are identified by the letters A (hydrolyzed collagen recipient group), B (PRP recipient group) and C (hyaluronic acid recipient group). Cards will be recorded and these cards will be placed in sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher, the patient, the data analyst and the outcome evaluator are kept blind and are not aware of the intervention performed on each group of patients, and only the final data are assigned to the first, second, and third groups of random numbers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-09-10, 1402/06/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.317

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

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

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

Assessment of knee pain

Timepoint

At the beginning of the study (before intervention) and 4 weeks and 24 weeks after the intervention

Method of measurement

Visual analogue scale (VAS), WOMAC and Lequesne index questionnaire

2**Description**

Assessing the patient's performance in daily tasks

Timepoint

At the beginning of the study (before intervention) and 4 weeks and 24 weeks after the intervention

Method of measurement

Using the WOMAC questionnaire

3**Description**

Assessment of morning stiffness

Timepoint

At the beginning of the study (before intervention) and 4 weeks and 24 weeks after the intervention

Method of measurement

Using the WOMAC and Lequesne index questionnaire

Secondary outcomes**1****Description**

The degree of patient's satisfaction with the treatment

Timepoint

At the beginning of the study (before intervention) and 4 weeks and 24 weeks after the intervention

Method of measurement

5-items questionnaire

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

Intervention group: includes 40 patients who are treated with CHondroGrid (Bioteck) made of hydrolyzed collagen diluted in 2 cc of normal saline on three injections with two-week intervals.

Category

Treatment - Drugs

2**Description**

Intervention group: Includes 40 patients who are treated with intraarticular injection of 5 cc of PRP in three injections with two-week intervals.

Category

Treatment - Drugs

3**Description**

Intervention group: includes 40 patients who are treated with 2 cc of hyaluronic acid (Hyalgan) with a molecular weight of 500000-730000 daltons in three injections with two-week intervals intra-articularly.

Category

Treatment - Drugs

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

Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeissadat

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Shahid Modarres hospital , Kaj Square, Sa'adat abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Nazari Noudoshan

Position

Resident of Physical medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Postal code

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All the data of people participating in this study can be shared after deidentifying people

When the data will become available and for how long

The access period starts one year after the results are

published

To whom data/document is available

Data of this study will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If the goal of the researchers is to conduct a systematic review and meta-analysis on the data, the non-identifiable data of the patients will be provided to the researchers.

From where data/document is obtainable

By sending an email to alin7093@gmail.com

What processes are involved for a request to access data/document

The given request should contain information about his/her affiliation, phone number, e-mail and the reason for his/her request. If these items are presented and the information related to the applicant's plan is registered and confirmed in the PROSPERO system, the information will be provided to the applicant.

Comments