Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Safety and efficacy evaluation of intra-articular knee transplantation of three consecutive doses of Platelet-Rich Plasma in patients with knee osteoarthritis: Interventional clinical trial, Phase II

Protocol summary

Study aim

Determining the safety of intra-articular injection of three consecutive doses of platelet-rich plasma derived from non-autologous umbilical cord blood in patients with knee osteoarthritis

Design

Randomised controlled trial, with parallel groups, double-blind, phase 1/2 on 30 patients, randomized using Random allocation software

Settings and conduct

Patients are injected 3 times at 0-, 1-, and 2-month intervals in the operating room at Royan Clinic. Patients will be monitored for up to one year. For the purpose of blinding, the biological product will be prepared in the form of disposable 5 cc syringes that look exactly like each other with a special label. Only the doctor and the person in charge of the transplant will know the type of treatment received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 45-70, years of knee osteoarthritis with grade 2 and 3 MRI diagnosis, knee pain ≥4, completion of informed consent form Exclusion criteria: pregnant, lactating women or disabled adults, intrachondral injection within the last 2 months, Abnormal hematological or biochemical tests, History of any type of neoplasm, Aspirin consumption one week before cell injection, History of coagulopathy or use of anticoagulant drugs, Positive viral tests, Rheumatoid arthritis or other autoimmune diseases involving joints, History of corticosteroid use in 3 last month

Intervention groups

Control group: patients receiving 3 doses of hyaluronic acid; Test group: patients receiving 3 doses of PRP.

Main outcome variables

Adverse events (AEs) and severe adverse events (SAEs), WOMAC, VAS, SF-36, Articular cartilage thickness

General information

Reason for update

This update is being made to correct administrative data-entry errors in the trial registration. During registration, some information from a separate but similar MSC study was inadvertently entered into the record of this PRP study. Specifically, the investigational product was incorrectly described as MSCs in one section, whereas the correct intervention is platelet-rich plasma (PRP). In addition, the injection interval was incorrectly recorded as every two months, whereas the ethics-approved PRP protocol specifies one injection per month. These corrections do not represent changes to the approved protocol. The ethics-approved protocol has consistently specified PRP as the intervention and monthly administration as the treatment schedule. The registry is being updated solely to ensure that the registered information accurately corresponds to the protocol approved by the Research Ethics Committee.

Acronym

PRP : Platelet Rich Plasma

IRCT registration information

IRCT registration number: **IRCT20211102052944N2**
Registration date: **2023-02-09, 1401/11/20**
Registration timing: **prospective**

Last update: **2026-07-14, 1405/04/23**
Update count: **1**

Registration date

2023-02-09, 1401/11/20

Registrant information

Name

Elaheh Afzal

Name of organization / entity

Royan stem cell technology company

Country

Iran (Islamic Republic of)

Phone
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Email address
e.afzal@rsct.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-21, 1402/02/01
Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Safety and efficacy evaluation of intra-articular knee transplantation of three consecutive doses of Platelet-Rich Plasma in patients with knee osteoarthritis: Interventional clinical trial, Phase II

Public title
Effect of PRP derived from umbilical cord blood in the treatment of knee arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
45-70 years Kellgren and Lawrence grade of both knees between 2 and 3 knee pain for at least 4 months that has not responded to common medical and physical therapies. Visual analogue score ≥ 4 Informed consent
Exclusion criteria:
Pregnancy or lactation Presence of any concomitant knee injury that causes pain or swelling (eg, ligament damage or meniscal tear) Intra-articular injection of hyalgan or steroid drugs during the last 2 months Malalignment of the knee joint more than 15 degrees (diagnosis with triple joint view radiography) Documented uncontrolled underlying diseases (including diabetes (HbA1c ≥ 8), heart failure (EF<45%), kidney failure (Cr>2), liver failure (AST, ALT>100) The existence of blood or cardiovascular diseases, infections and weak immunity, neoplasm, etc., which interfere with the evaluations. History of orthopedic surgery in the spine or lower limbs Osteoarthritis of the hip or ankle joint Known allergy to hyaluronic acid products Taking aspirin one week before cell injection History of coagulopathy or use of anticoagulant drugs
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to the control and PRP groups. The method of random assignment of these two groups is block randomization. The size of the blocks is 6 people, and using Random allocation software, the sequence of assigning patients to the groups is determined, and this sequence will be kept by the transplant manager.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind study. Patients and study analysts will be unaware of the type of treatment assigned. To achieve this goal, by using a biological product in the form of disposable 5 cc syringes that are already filled by the nurse and are completely "similar" to the type of treatment received, to blind the participants in the study. Also, the people who apply the treatment will be different from the people who are responsible for examining and evaluating the patients, and the biological product packages will be labeled according to a specific code. Only the doctor and the person in charge of the transplant will know the type of treatment the patients receive.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Royan Institute-Academic Center for Education, Culture and Research
Street address
No. 24, Research Ethics Committee, Royan Research Institute, East Hafez Alley, Bani Hashim Square, Bani Hashim St, Resalat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1665666311
Approval date
2023-01-29, 1401/11/09
Ethics committee reference number

IR.ACECR.ROYAN.REC.1401.110

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Adverse events and severe adverse events
Timepoint
0, 1, 2, 6, 9, and 12 months after intervention
Method of measurement
Clinical signs and questionnaire

2

Description
Western Ontario and McMaster Universities Osteoarthritis Index
Timepoint
Baseline and 1, 2 , 6, 9, and 12 months after intervention
Method of measurement
WOMAC Questionnaire

3

Description
Visual analog scale
Timepoint
Baseline and 1, 2 , 6, 9, and 12 months after intervention
Method of measurement
Visual Analogue Scale Questionnaire

4

Description
Disability index
Timepoint
Baseline and 6, 9, and 12 months after intervention
Method of measurement
Short Form Health-36 Questionnaire

5

Description
Articular cartilage thickness
Timepoint
Baseline and 12 months after intervention
Method of measurement
Magnetic resonance imaging

Secondary outcomes

1

Description
Adverse events and severe adverse events
Timepoint
0, 1, 2, 6, 9, and 12 months after intervention
Method of measurement
Clinical signs and questionnaire

Intervention groups

1

Description
Control group: Patients receiving 3 doses of Hyaluronic acid. The procedure will be performed in such a way that patients are injected intra-articular injection of 2 cc of hyaluronic acid in three times at 0,1 and 2 months intervals in the operating room of Royan Clinic. At the time of injection, the patient's knee is sterilized and the orthopedic surgeon will inject into the joint space under sterile conditions. After the injection, the patient is monitored for 2 hours and after this period, if there is no problem with the necessary medication and care instructions and explanation of warning signs will be discharged.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: patients receiving 3 doses of PRP. The procedure of the intervention will be that the patients will be injected with 5 cc of PRP derived from non-autologous umbilical cord blood in the operating room of Royan Clinic on three occasions with intervals of 0, 1 and 2 months. . On the day of the knee transplant, the patient's knee will be sterilized and the orthopedic surgeon will inject into the joint space under sterile conditions. After the injection, the patient will be observed for 2 hours and after this period, if no problem occurs, he will be discharged with the necessary medication and care instructions and an explanation of the warning signs.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Cell Therapy Center
Full name of responsible person
Dr. Masoud Vosough
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No.9, Shaghayegh Dead End, Bani Hashem Sq., Bani Hashem St., Resalat St.,

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Royan Stem Cell Technology Company
Full name of responsible person
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No. 24, East Hafez Alley, Bani Hashim Square, Bani Hashim St, Resalat Highway, Tehran, Iran.
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Email
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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
Royan Stem Cell Technology Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
Morteza Zarrabi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Elaheh Afzal
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Research Assistance
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Medical Genetics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The information and data will be published as an article after reviewing and verifying them. All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

After following the patients and collecting data, checking the safety and efficiency of cell injection and then writing the article, which is done about 3 months after the follow-up, the data file will be published.

To whom data/document is available

Access to the documents of this research is not limited to academic and scientific researchers, and specialists working in other centers can also access these documents.

Under which criteria data/document could be used

Designing similar studies in other academic centers

From where data/document is obtainable

e.afzal@rsct.it

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

Within 1-2 months after application. Applicants for access to the research documents must provide evidence of their activity in the relevant field and their need for this data along with their application email.

Comments