

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effects of Orthokine(Autologous Conditioned Serum), platelet rich plasma(PRP) and Prolotherapy on pain and function of patient with Knee osteoarthritis: A Randomized Clinical Trial

Protocol summary

Study aim

Effect of Orthokine(Autologous Conditioned Serum), platelet rich plasma(PRP) and Prolotherapy on pain and function of patient with Knee osteoarthritis

Design

A single blind controlled randomized clinical trail with three parallal groups

Settings and conduct

The target population are all patients with knee osteoarthritis referred to the specialized physical medicine clinics of Tabriz University of Medical Sciences. They will be enrolled in the study if they have included criteria and have not excluded criteria. Sampling will be done by convenience non randomized method. For concealment of allocation, the name of intervention group will be placed inside a consecutively numbered sealed opaque envelopes.

Participants/Inclusion and exclusion criteria

inclusion:Age between 40-75 years, Grade I-II-III of OA (Kellgren-Lawrence), Pain severity >4 in a 10-numbered linear scale. Pain in more than 3 months!

Exclusion:Grade IV of OA ,Multifactorial Knee Pain ,Lower limb Deformity.

Intervention groups

Control group: intra articular knee injection of dextrose prolotherapy once a week for three weeks under ultrasound guidance through suprapatellar pouch, Intervention group: platelet rich plasma(PRP), two times intra knee articular injection of 2 ml platelet rich plasma with a seven day interval, Intervention group: Two times injection of 2 ml Autologous Conditioned Serum under ultrasound guidance through suprapatellar pouch with a seven day interval

Main outcome variables

pain severity, Function condition

General information

Reason for update

Correction of start date and completion of study

Acronym

IRCT registration information

IRCT registration number: **IRCT20100720004422N6**

Registration date: **2019-08-07, 1398/05/16**

Registration timing: **retrospective**

Last update: **2020-02-22, 1398/12/03**

Update count: **1**

Registration date

2019-08-07, 1398/05/16

Registrant information

Name

Seyed Kazem Shakouri

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3518

Email address

shakourik@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-08-01, 1398/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Orthokine(Autologous Conditioned Serum), platelet rich plasma(PRP) and Prolotherapy on pain and function of patient with Knee osteoarthritis: A Randomized Clinical Trial

Public title

Camparison Effects of Autologous Conditioned Serum, platelet rich plasma and Prolotherapy in treatment of Knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 40-75 Grade I-II-III of OA (Kellgren-Lawrence) Pain severity >4 in a 10-numbered linear scale Pain in more than 3 months

Exclusion criteria:

Grade IV of OA Multifactorial Knee Pain Lower limb Deformity

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients were randomly assigned in to three groups receiving: 1) Dextrose Prolotherapy; 2) Autologous Conditioned Serum; 3) platelet rich plasma. Allocation sequence will be determined using random blocking of blocks 6 and 9 in Random Allocation Software (RAS) using a 1:1:1 assignment ratio. To conceal the allocation, the name of intervention group will be placed inside a consecutively numbered sealed opaque envelopes. Preparation of envelopes and sequence generation will be done by a person not involved in participant recruitment or data collection.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because of blood sampling in the two groups, we can not able to blind all participants. Syringes with the same size and covered with foil will be prepared by a clinical staff who will not performed injections. Therefore, the investigator will not aware of the injectable drug type. also, out come assessor and statistical analyst will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Regional Ethics committee of Tabriz University of Medical Science

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht Str

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.TBZMED.REC.1397.722

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**

Functional condition

Timepoint

At the beginning of the study(before the intervention) , one and six months after treatment

Method of measurement

Western Ontario and McMaster (WOMAC) questionair

2**Description**

pain severity

Timepoint

Visual Analogue Scale (VAS) and Western Ontario and McMaster (WOMAC) questionnaire

Method of measurement

At the beginning of the study(before the intervention)

and one and six months after treatment

Secondary outcomes

empty

Intervention groups

1

Description

Control group: intra articular knee injection of dextrose prolotherapy (mixture of 2ml dextrose 50% and 2 ml sterile water and 1ml Lidocaine)will be done weekly for 3 weeks under ultrasound guidance through suprapatellar pouch

Category

Treatment - Other

2

Description

Intervention group: platelet rich plasma(PRP), two times intra knee articular injection of 2 ml platelet rich plasma will be done for participants with a seven day interval.(each times, 20 ml blood will be centrifuged 13 mins at 1600 rpm, then 7 mins at 3500 rpm)

Category

Treatment - Other

3

Description

Intervention group:Orthokine(Autologous Conditioned Serum),2 ml Autologous Conditioned Serum will be injected to knee under ultrasound guidance through suprapatellar pouch with a seven day interval for two times.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Alireza Pishgahi

Street address

Golgasht Str.,Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 1134

Email

alirezapishgahi1364@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Vice Chancellor for Research (VCR), Central building
No. 2, Tabriz University of Medical Sciences,
Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 7310

Email

ajouyban@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Pishgahi

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Golgasht Str., Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 914 218 3786

Email

alirezapishgahi1364@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Pishgahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Golgasht Str.,Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 914 218 3786

Email

alirezapishgahi1364@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Pishgahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Golgasht Str.,Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 914 218 3786

Email

alirezapishgahi1364@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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