Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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, Functinal 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

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Iran (Islamic Republic of)

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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 osteoartritis

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
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Golgasht Str.,Azadi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
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Vice Chancellor for Research (VCR), Central building No. 2, Tabriz University of Medical Sciences, Golghasht Ave.
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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
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
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Person responsible for updating data

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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