Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The effects of Autologous Conditioned Serum therapy on chronic knee osteoarthritis

Protocol summary

Study aim

The effects of Autologous Conditioned Serum therapy on chronic knee osteoarthritis

Design

Fifteen patients were selected based on radiologic findings randomly with the period of three months of knee osteoarthritis are classified. Patients were randomly assigned to receive 10 cc of blood from a cobital vein injection and collected in an ACS syringe manufactured by Pishtaz teb zaman Co. and used to produce ACS. For this purpose, blood in the syringe is incubated for 24 hours at 37 ° C to release growth and anti-inflammatory factors,The blood is then centrifuged at 3000 g for 10 minutes to remove the ACS. After separation, the ACS is filtered with a 0.22 µm filter and stored at -80 ° C until use.

Settings and conduct

The following items for the patients who are most relevant, recorded: 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM). After producing ACS and quality control, patients will be referred to the Rehabilitation and Physical Medicine Department of the Shahid Madani Hospital for the injection of ACS by supralateral in the knee. A second injection is repeated at intervals of 21 days. Then, in order to evaluate the effect of ACS on patients in the intervals of 1, 3 and 6 months after the first injection, the cases mentioned above will be recorded.

Participants/Inclusion and exclusion criteria

A total of 15 patients were selected based on radiologic findings with a period of three-month symptoms of knee osteoarthritis.

Intervention groups

ACS treatment group; control group without any treatment

Main outcome variables

1- Determining knee pain by VAS in all phases of clinical trial; 2-Determination of knee function by WOMAC and KOOS in all phases of clinical trial; 3-Determine the range of knee motion by manual joiniometry in all phases of the trial

General information

Reason for update

Acronym

OA

IRCT registration information

IRCT registration number: **IRCT20160422027520N13**
Registration date: **2019-08-14, 1398/05/23**
Registration timing: **prospective**

Last update: **2019-12-22, 1398/10/01**
Update count: **1**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of Autologous Conditioned Serum therapy on chronic knee osteoarthritis

Public title
Treatment of chronic knee osteoarthritis with Autologous Conditioned Serum
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women between the ages of 18 and 75 with OA diagnosis based on the American College of Rheumatology Analog scale of knee pain (VAS) equal to or greater than 2.5 People with at least 4 months of history of pain or swelling in one or both knees Radiological classification scale Kellgren-Lawrence 1 or 2 The availability of individual during the study period BMI Between 20 and 35
Exclusion criteria:
People under the age of 18 and over 75 years Pregnant women or women who are breastfeeding People with malignancy,People with severe heart disease, uncontrolled diabetes mellitus, rheumatoid arthritis, hemorrhagic diseases, history of anemia, arthritis, fibromyalgia and chronic fatigue syndrome Those linked to acetaminophen or Vicodin or a history of drug misuse History of cortisone injections in the last 6 weeks The use of non-steroidal anti-inflammatory drugs 1 week ago Having hemoglobin less than 11 g / dl and platelet count less than 150000 / mμ The use of inhibitors of platelet aggregation and anti-coagulation such as heparin History of knee surgery in the last 3 months Extraordinary deformation (varus >5°, valgus >5°)
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The study participants were unaware of their placement in the study group (Autologous Conditioned Serum or normal saline).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences , Daneshghah st, Tabriz,
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2019-07-15, 1398/04/24
Ethics committee reference number
IR.TBZMED.REC.1398.466

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
M15.4
ICD-10 code description
Erosive (osteo)arthritis

Primary outcomes

1

Description
Determining knee pain by VAS in all phases of clinical trial
Timepoint
Before injection and 1, 3 and 6 months after the first injection
Method of measurement
Questionnaire (VAS)

2

Description
Determination of knee function by WOMAC and KOOS in all phases of clinical trial
Timepoint
Before injection and 1, 3 and 6 months after the first

injection

Method of measurement

Questionnaire (WOMAC), Questionnaire (KOOS)

3

Description

Determine the range of knee motion by manual joiniometry in all phases of clinical trial

Timepoint

Before injection and 1, 3 and 6 months after the first injection

Method of measurement

Range of motion (Degree)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fifteen patients with knee osteoarthritis receive Autologous Conditioned Serum as the intervention group. Initially, receive informed consent from the patients and the following will be recorded for these patients who meet the inclusion criteria: 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM). In this group of patients, 10 ml of blood was taken by ACS-specific syringe manufactured by Pishtaz teb zaman CO. and after incubation of this syringe according to protocol kit, we separate the ACS. The ACS is then injected by a physician into one of the two knees of the patient with knee osteoarthritis. The injection volume of ACS is 2 cc.Repeat injections twice again 21 days apart.Then, in order to evaluate the effect of ACS on patients in the intervals and Compare it with another patient's knees who received normal saline, 1, 3 and 6 months after the first injection, 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM) will be recorded.

Category

Treatment - Other

2

Description

Control group: Fifteen patients with knee osteoarthritis receive normal saline (NS) as the intervention group. Initially, receive informed consent from the patients and the following will be recorded for these patients who meet the inclusion criteria: 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM). Then NS by the physician is injected into another patient's knee. Repeat injections twice again 21 days apart. Then, in order to evaluate the effect of NS on patients in the intervals and Compare it with another patient's knees who received ACS, at 1, 3 and 6 months after the first injection, 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM) will be recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital, Tabriz

Full name of responsible person

Mehdi Yousefi, Ph.D Of Medical Immunology

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Shahid Madani Hospital, Golbad Avenue, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pishtaz teb zaman Co.

Full name of responsible person

Behrooz Hajeian tehrani

Street address

Golha, Pishtaz teb zaman Co.

City

tehran

Province

Tehran

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1494734463

Phone

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mehdi_yusefi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pishtaz teb zaman Co.

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Position

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Latest degree

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Other areas of specialty/work

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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