

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Assessing the effects of autologous conditioned serum (orthokine) on pain intensity, clinical symptoms, quality of life and work productivity in patients with knee osteoarthritis

Protocol summary

Summary

This study is a before-after interventional study which is conducted in knee osteoarthritis patients referred to the clinics related to Tabriz University of Medical Sciences. 50 patients are selected randomly according to the inclusion/exclusion criteria and the written informed consent obtain. Orthokine injection 2 ml each time (4-6 injection) are conducted. Patients are followed 3, 6, 12, 24 and 48 weeks and 2 year and 3 years after injection and related questionnaires are completed for them. Pain intensity is measured using NRS. Clinical symptoms (pain, stiffness and physical function) are determined using WOMAC. Quality of life is determined using SF-36 and work productivity is measured with WPAL.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707046934N3**
Registration date: **2017-07-23, 1396/05/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-23, 1396/05/01

Registrant information

Name

Susan Kolahi

Name of organization / entity

Tabriz Medical Science University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences- Drug applied Reseach center

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effects of autologous conditioned serum (orthokine) on pain intensity, clinical symptoms, quality of life and work productivity in patients with knee osteoarthritis

Public title

Assessing the effects of autologous conditioned serum (orthokine) on pain intensity, clinical symptoms, quality of life and work productivity in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 30-80, having knee osteoarthritis grade II-IV according to Kellgren-Lawrence, having moderate to severe knee pain in the past 4 weeks, being interested to participate in the study. Exclusion criteria: history of knee surgery or arthroscopy in the last six months, history of trauma, history of knee injection

during the past 3 months (steroids, hyaluronate, PRP, ACS, ACP), having rheumatoid arthritis or other systemic bone or joint diseases, active inflammation of patellofemoral, BMI>30 kg/m², malignancy, infection, pregnancy

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Postal code**Approval date**

2017-05-08, 1396/02/18

Ethics committee reference number

IR.TBZMED.REC.1396.127

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

Knee osteoarthritis

ICD-10 code

M15, M16,

ICD-10 code description

Gonarthrosis [arthrosis of knee]

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

Pain intensity

Timepoint

baseline, weeks 3,6,12,24, 48 and after 2 and 3 year

Method of measurement

NRS

2**Description**

clinical symptoms (pain, stiffness, daily function)

Timepoint

baseline, weeks 3,6,12,24, 48 and after 2 and 3 year

Method of measurement

WOMAC

3**Description**

Quality of life

Timepoint

baseline, weeks 3,6,12,24, 48 and after 2 and 3 year

Method of measurement

SF-36

4**Description**

Work Productivity and Activity Impairment

Timepoint

baseline, weeks 3,6,12,24, 48 and after 2 and 3 year

Method of measurement

WPAI

Secondary outcomes

empty

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

Orthokine injection 2 ml 4-6 times

Category

Treatment - Other

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

Emam Reza hospital- Tabriz University of Medical Sciences

Full name of responsible person**Street address****City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Rashidi

Street address

Golgasht St.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Drug applied research center

Full name of responsible person

Dr. Hossein Babaei

Street address

Golgasht St.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Drug applied research center

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sousan Kolahi

Position

Rheumatologist

Other areas of specialty/work

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Full name of responsible person

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty