

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the simultaneous effect of orthokine therapy and ozone therapy in the treatment of patients with knee osteoarthritis: A randomized controlled trails

Protocol summary

Study aim

Orthokine therapy and ozone therapy in knee osteoarthritis

Design

A clinical trial with parallel groups, double-blind, block randomization, phase 3 on 120 patients with knee arthritis, in one group orthokine will be injected with placebo and in the other group orthokine will be injected with ozone.

Settings and conduct

In this double-blind clinical trial study, 120 people with knee arthritis referred to the pain clinic of Shahid Beheshti Hospital, who were treated with orthokine therapy by random block method, will be divided into two groups of 60 people: Group 1: including 60 people under orthokine therapy with ozone Group 2: including 60 people under orthokine therapy with placebo Treatment protocol of the first group: Ertokine including 4 injections of 2 ml of IL-1Ra on the first, seventh, fourteenth and twenty-first days of treatment, ozone including 3 injections of 10 ml of ozone (30 g/ml) + 5 ml of lidocaine % 1 to the knee joint on the first day of treatment, one month after the first injection and two months later. The treatment protocol of the second group will be orthokine therapy with placebo in three times. Before the treatment and 1, 3 and 6 months after the treatment, the pain intensity of the patients will be measured using the WOMAC questionnaire.

Participants/Inclusion and exclusion criteria

All patients with knee osteoarthritis with grades 2 and 3

Intervention groups

1)orthokine including 4 injections of 2 ml of IL-1Ra on the first, seventh, fourteenth and twenty-first days of treatment, ozone including 3 injections of 10 ml of ozone (30 g/ml) + 5 ml of 1% lidocaine to the knee joint will be done on the first day of treatment, one month after the first injection and two months later. The treatment

protocol of the second group will be 4 injections of orthokin, and receiving placebo on three times.

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

OOO

IRCT registration information

IRCT registration number: **IRCT20230311057677N1**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **prospective**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

Name

Zahra Hajrezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the simultaneous effect of orthokine therapy and ozone therapy in the treatment of patients with knee osteoarthritis: A randomized controlled trials

Public title

Simultaneous treatment of orthokine therapy and ozone therapy in knee arthrosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with knee osteoarthritis with grades 2 and 3 in the Kellgren and Lawrence criteria

Exclusion criteria:

The presence of coagulation disorders Taking anticoagulants Infection at the injection site

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using the balanced block randomization method with a block size of 6. The random sequence is generated by an epidemiologist by running an online program on the website (<https://www.sealedenvelope.com>). Allocation concealment is also guaranteed due to the use of special codes generated by the website

Blinding (investigator's opinion)

Double blinded

Blinding description

It is explained to the patients that the injection is placed intra-articularly and the patient is lying supine and the injection is performed in the intrapatellar area, and the patients were unaware of the content of the injected substance. He will complete the pain assessment questionnaire.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Qom University of Medical Sciences

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Qom Univrsity for Medical Science, Saheli street

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3719964797

Approval date

2023-01-30, 1401/11/10

Ethics committee reference number

IR.MUQ.REC.1401.157

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

osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

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

Pain Intensity

Timepoint

Before intervention and 1-3 -6 months after the start of the intervention

Method of measurement

WOMAC (Western Ontario and McMaster University) questionnaire

Secondary outcomes

empty

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

Intervention group 1: Patients receiving orthokine therapy with ozone. Artokine includes 4 injections of 2 ml of IL-1Ra on the first, seventh, fourteenth and twenty-first days of treatment, ozone includes 3 injections of 10

ml of ozone (30 g/ml) + 5 ml of 1% lidocaine to the knee joint in The first day of treatment will be done one month after the first injection and two months later.

Category

Treatment - Drugs

2**Description**

The second intervention group: Ortokine including 4 injections of 2 ml of IL-1Ra on the first, seventh, fourteenth and twenty-first days of treatment and receiving placebo on three occasions

Category

Treatment - Drugs

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

Shahid Beheshti Hospital, Qom

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Ghoum 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**

Ghoum University of Medical Sciences

Full name of responsible person

Zahra Hajrezaei

Position

Medical Student

Latest degree

A Level or less

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