

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison prolotherapy with erythropoietin and ozone with injections of sodium hyaluronate, chondroitin sulfate and ozone in reducing pain in patients with knee osteoarthritis

Protocol summary

Study aim

Comparison of prolotherapy with erythropoietin and ozone with injections of sodium hyaluronate, chondroitin sulfate and ozone in reducing pain in patients with knee osteoarthritis

Design

The clinical trial without control group, with parallel groups, non blinded, non-randomized, and in phase 3 of clinical trial studies.

Settings and conduct

This study was carried out as a non blinded clinical trial at the pain clinic of zahedan university of medical sciences. Patients with inclusion criteria are considered as study group, in this study 100 cases with inclusion criteria were selected. They divided into two intervention group.

Participants/Inclusion and exclusion criteria

Patients with knee osteoarthritis, informed consent to participate in the study, complications of pain, crepitus and knee stiffness for at least three months and visual analogue scale more than 3 included for study, and patients with infection, any knee injections in the last three months, diabetes mellitus, history of rheumatoid arthritis, injection of steroid drugs over the past two months, drug addiction, arthroplasty, body mass index more than 42, history of cancer, pregnancy, radiculopathy, neuropathy and nnticoagulant use excluded from study.

Intervention groups

In the first intervention group, erythropoietin was used twice with a dose of 4000 international units / ml made in Iran in Razavi Pharmaceutical Company in collaboration with the Austrian company with 7 cc ozone 25 µg / ml, in the second intervention group, 3 cc injection of a mixture of sodium hyaluronate and chondroitin sulfate solution produced by Raha Pharmaceutical Company in collaboration with France was used once with 7 cc ozone

25 µg / ml.

Main outcome variables

Knee pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190503043450N1**

Registration date: **2020-01-18, 1398/10/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-18, 1398/10/28**

Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Seyyed Amirreza Alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5575

Email address

alavi.amirreza@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison prolotherapy with erythropoietin and ozone with injections of sodium hyaluronate, chondroitin sulfate and ozone in reducing pain in patients with knee osteoarthritis

Public title

Comparison of the effect of erythropoietin and ozone on joint function in patients with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Knee osteoarthritis Informed consent to participate in the study Complications of pain, crepitus and knee stiffness for at least three months Visual Analogue Scale score more than 3

Exclusion criteria:

infection Any knee injections in the last three months Diabetes mellitus History of rheumatoid arthritis Injection of steroid drugs over the past two months. Drug addiction Arthroplasty Body mass index more than 42 History of cancer Pregnancy Radiculopathy Neuropathy Anticoagulant use

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zahedan University of Medical

Sciences

Street address

9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-06-30, 1398/04/09

Ethics committee reference number

IR.ZAUMS.REC.1398.124

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

Knee osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

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

knee pain

Timepoint

Measurement of pain before injection and 3, 6, 9 and 12 months after injection

Method of measurement

With visual analogue scale

Secondary outcomes

empty

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

Intervention group 1: Erythropoietin injection twice with 3 weeks intervals with dose as 4000 International Units per milliliter made in Iran in Razavi pharmaceutical company in cooperation with Austria country, with 7 cc ozone 25 µg / ml in knee joint.

Category

Treatment - Drugs

2**Description**

Intervention group 2: Injection of 3 cc mixture of sodium hyaluronate and chondroitin sulfate solution produced by Raha Pharmaceutical Company in collaboration with

France country once with 7 cc ozone 25 µg / ml in knee joint.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain Clinic of Zahedan University of Medical Sciences

Full name of responsible person

Asadollah Shakeri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noormohammad Bakhshani

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Bakhshani@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Amirreza Alavi

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Amirreza Alavi

Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Main outcome information

When the data will become available and for how long

12 months after publishing results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

To verify the results and prevent repetition in similar
research

From where data/document is obtainable

Library and website of Zahedan University of Medical
Sciences

What processes are involved for a request to access data/document

Refer to the library and website of Zahedan University of
Medical Sciences and have access to a maximum of one
week

Comments