

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

**City**

Zahedan

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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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Asadollahshakeri@zaums.ac.ir

**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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9816743463, Ali Ibn Abi Talib Hospital, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Amirrezaalavi@zaums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

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**Position**

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

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**Full name of responsible person**

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**Position**

Anesthesiology Resident

**Latest degree**

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**Other areas of specialty/work**

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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**