

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Compare the effect of ultrasound guided corticosteroid injection with ozone injection in patients with osteoarthritis of the knee.

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

The aim: compare the effect of ultrasound guided corticosteroid injection with ozone injection in patients with osteoarthritis of the knee. Study design: non random sampling; convenience sampling and then patients will be assigned to two groups by block randomization. the study is double blind (patient and analyzer). Population: patients with knee osteoarthritis referred to physical medicine clinics (Iran University of Medical Sciences). The main inclusion criteria: patients with mild to moderate OA of the knee (Kellgren Lawrence grade I, II and III); the absence of any acute or chronic infection; no history of any intra articular injection of the knee in three months ago; the absence of inflammatory articular disease and absence of contraindications of ozone therapy. The main exclusion criteria: the willingness of patients to exit from the study. Sample size: 30. Interventions: in initial time, 1 cc lidocaine 2% will be used for local anesthesia (skin) in both groups. then under sterile conditions, in one group 40 mg triamcinolone (1 cc) will be injected into the knee joint (under ultrasound guided in suprapatellar Pouch). in another group under sterile conditions, 10 cc oxygen ozone (O2O3), (15 mg / ml) under ultrasound guided (in suprapatellar pouch), will be injected into the joint. Outcomes: before injection , pain intensity (VAS) , WOMAC score, clinical assessment (range of motion), suprapatellar effusion (with ultrasound) in both groups will be determined and then this criteria evaluated at week, one month and three months post injection. the results will be compared before and after injection in each group and between the two groups.

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Arash Babaei-Ghazani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-10-23, 1395/08/02

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of ultrasound guided corticosteroid injection with ozone injection in patients with osteoarthritis of the knee.

Public title

Compare the effect of ozone injection with corticosteroid

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112724572N3**

Registration date: **2017-02-10, 1395/11/22**

injection on osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with mild to moderate OA of the knee (Kellgren Lawrence grade I, II and III); Knee pain for at least six months; Age 40 to 75 years; the absence of any acute or chronic infection; no pregnancy or lack of planning to get pregnant; no history of any intra articular knee injection in three months ago; The absence of inflammatory articular disease or secondary osteoarthritis; no history of knee surgery (3 months ago); no severe underlying disease such as uncontrolled diabetes; use of anticoagulants; lack of daily use of opioid and non opioid analgesics; absence of contraindications of ozone therapy (deficiency G6PD, uncontrolled hyperthyroidism, leukemia). Exclusion criteria: the willingness of patients to exit from the study at any stage of the study; not coming patients for follow up and evaluation during the follow up period; daily use of any type of analgesic medication by patients during the follow up period; occurring a pathology in the knee, such as meniscus tear during the follow up period; occurring 4th and 7th inclusion criteria, during the study.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Postal code

1449614535

Approval date

2016-10-22, 1395/08/01

Ethics committee reference number

IR.IUMS.REC 1395.9411524007

Health conditions studied

1

Description of health condition studied

Primary gonarthrosis, bilatera

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description

The severity of pain

Timepoint

Zero, one, four and twelve weeks after

Method of measurement

Visual Analog Scale(VAS)

2

Description

The severity of symptoms and functional limitations

Timepoint

Zero, one, four and twelve weeks after

Method of measurement

By using WOMAC questionnaire

3

Description

Sonographic criteria (efusion)

Timepoint

Zero, one, four and twelve weeks after

Method of measurement

By using sonographic device

4

Description

Range of motion

Timepoint

Zero, one, four and twelve weeks after

Method of measurement

Goniometer

Secondary outcomes

1

Description

Side effects

Timepoint

One and four weeks after

Method of measurement

Physical examination

Intervention groups

1

Description

Intervent group: ozon injection will be performed under the ultrasound guid in the knee joint which will be done by an experienced physical medicine and rehabilitation specialist; using supra patellar approach.

Category

Treatment - Other

2

Description

Control group: corticosteroid injection will be performed under the ultrasound guid in the knee joint which will be done by an experienced physical medicine and rehabilitation specialist; using supra patellar approach.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar hospital

Full name of responsible person

Dr. saeideh najarzadeh mehdikhani

Street address

Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Iran University of Medical Sciences

Full name of responsible person

Dr Motovalian

Street address

5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice President of Research Iran University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Saeideh najarzadeh mehdikhani

Position

Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Arash Babaei

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Associate Professor of Physical Medicine and Rehabilitation

Other areas of specialty/work

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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