Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112724572N3**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Arash Babaei-Ghazani

Name of organization / entity

Country

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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

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 questionnare

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