

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison the therapeutic effect of one-time with three-times ozone injection under ultrasound guidance in patients with knee osteoarthritis

Protocol summary

Study aim

Comparison the Therapeutic Effect of One-Time Injection with Three Ozone Under Sonography on Patients with Knee Strengthening

Design

Patients are randomly and evenly divided into two groups: group A or ozonotherapy group in one session; group B or ozone therapy group in three sessions. Before injection of one cc of lidocaine 2% for local skin anesthetic and the underlying tissues are used in both groups. Then, under sterile conditions, in a group of patients, a dose of 15g / ml (5 cubic cubic meters) of ozone-oxygen is injected into the knee joint (in one session) by ultrasound.

Settings and conduct

Patients are randomly divided into two groups: group A or ozone therapy group in one session and group B or ozone therapy group in three sessions

Participants/Inclusion and exclusion criteria

Knee osteoarthritis based on the CRC of the American College of Rheumatology in Grades 1, 2 and 3, consistent with the Lawrence-Kellergan Criteria; knee pain for at least six months; age 18 to 75 years old; the absence of any acute or chronic infection; no tend to become pregnant or not to decide on pregnancy; to tending to perform any intra-articular injection of the knee during the last three months; absence of joint inflammatory diseases or secondary osteoarthritis; no history of knee surgery; lack of severe underlying disease such as uncontrolled diabetes, anti-coagulant use, and no daily intake of opioid and non-opioid analgesics.

Intervention groups

Group A or ozone therapy group in a session-group B or ozone therapy group in three sessions.

Main outcome variables

Severity of pain; knee range of motion; individual performance

General information

Reason for update

Correction of expected date of start and end of recruitment of patients. Correction of persons who are blinded.

Acronym

IRCT registration information

IRCT registration number: **IRCT20151017024572N18**

Registration date: **2018-09-01, 1397/06/10**

Registration timing: **prospective**

Last update: **2020-01-19, 1398/10/29**

Update count: **1**

Registration date

2018-09-01, 1397/06/10

Registrant information

Name

Arash Babaei-Ghazani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6435 2683

Email address

babaei-ghazani.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effect of one-time with three-times ozone injection under ultrasound guidance in patients with knee osteoarthritis

Public title

Comparison of ozone effect on knee osteoarthritis

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 old 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

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are randomly divided into two groups in closed packaging

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

Province

Tehran

Postal code

1449614535

Approval date

2018-07-23, 1397/05/01

Ethics committee reference number

IR.IUMS.REC.1397.120

Health conditions studied

1

Description of health condition studied

Primery gonrthrosis,bilateral

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

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 questioner

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

5

Description

Side effects

Timepoint

one, four weeks after

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervent group: three times ozon injectione with a one-week interval by a physician and rhabilitation spesialist under the ultrasound guide in the knee joint through a supra patellar approach

Category

Treatment - Other

2

Description

Control 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 specialis.using supra patellar approach

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar hospital

Full name of responsible person

Dr. Vajihe Alishahi

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

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Full name of responsible person

Dr. Motovalian

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Vajihe Alishahi

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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

Position

Associate Professor of Physical Medicine and
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available