

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effects of paraspinal ozone injection and the effects of physiotherapy on chronic non-radicular low back pain

Protocol summary

Study aim

Comparison of the effects of paraspinal ozone injection and physiotherapy in chronic non-radicular low back pain

Design

It is a randomized clinical trial with parallel groups, the study population of 64 patients referred to Firoozgar and Rasoul Akram hospitals.

Settings and conduct

The study population is patients referred to the clinic of physical medicine and rehabilitation of Firoozgar and Rasoul Akram hospitals in Tehran. Patients whose complaints are chronic non-radicular low back pain are examined and approved by a physical medicine and rehabilitation specialist, and if there are inclusion criteria, after completing the consent form, they are randomly admitted to one of the injection or physiotherapy groups. This study will be performed as a follow-up for one month and three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients complaining of chronic non-radicular low back pain. Exclusion criteria: radicular low back pain and neurological symptoms, patients who have undergone injections of any drug or acupuncture for the lower back in the past three months, and fractures, tumors, infections

Intervention groups

Intervention group: Ozone injection is done in three sessions in such a way that 10 cc of ozone (15 micrograms) with 2 cc of lidocaine with needle G 22 with lateral approach of 2 cm spinus process routinely at maximum tolerance points (Multi level treatment one level Above and below the affected surface) or the paraspinal resuscitation area of both sides is injected in area 4 L5-L and L5-S1. After the injection, it is recommended to do exercise at home. Control group: undergoes 10 sessions of physiotherapy, which includes surface and deep heat, infrared lamp, tens and exercise.

Main outcome variables

Visual analog Scale, Evaluate daily activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049512N1**

Registration date: **2020-12-14, 1399/09/24**

Registration timing: **prospective**

Last update: **2020-12-14, 1399/09/24**

Update count: **0**

Registration date

2020-12-14, 1399/09/24

Registrant information

Name

Mahdieh Saki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1000

Email address

saki.ma@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of paraspinal ozone injection and the effects of physiotherapy on chronic non-radicular low back pain

Public title

Comparison of the effects of paraspinal ozone injection and the effects of physiotherapy on chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

chronic low back pain for more than 6 weeks
nonradicular chronic low back pain Age 20 to 60 years
VAS is more than equal to 4 No contraindications to injections No contraindications to physiotherapy Failure to perform epidural and paraspinal injections in the last three months Failure to respond to medical treatment for more than two weeks The patient's desire to participate in the research project

Exclusion criteria:

Radicular pain Neurological signs and symptoms that indicate nerve root involvement Vascular malformation Tumor Fracture Infection Diffuse idiopathic skeletal hyperstosis Injectable treatment with any type of medication or acupuncture for the lower back during the last three months History of spinal surgery Bleeding disorders or the use of anticoagulants and hemorrhages other than aspirin Topical allergy to anesthetics pregnancy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block Randomization unit: individual Randomization tool: Random number tables

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 Iran University of Medical Sciences

Street address

School of Medicine, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2020-11-04, 1399/08/14

Ethics committee reference number

IR.IUMS.FMD.REC.1399.469

Health conditions studied

1

Description of health condition studied

Nonradicular chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Visual analog scale

Timepoint

Before ozone injection and physiotherapy, After doing it, one month and three months later

Method of measurement

VAS ruler

2

Description

Evaluate daily activities

Timepoint

Before injection and physiotherapy and three months after injection and physiotherapy

Method of measurement

Modified Oswestry questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 10 cc of ozone (15 micrograms) with 2 cc of lidocaine in the paraspinal region of both sides with needle 22-G in completely sterile conditions with lateral approach 2 cm spinus process routinely in the paraspinal region on both sides of maximum tenderness points (Multi level treatment Level up and down the affected surface or in areas 4 L5-L and L5-S1. The injection is given three times a week.

Category

Treatment - Drugs

2

Description

Control group: undergo 10 sessions of physiotherapy for 3 weeks, which includes surface and deep heat, infrared lamp, tens and exercise.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital, Tehran

Full name of responsible person

Gholamreza raissi

Street address

Firoozgar Hospital, Beh Afarin Street, Valiasr square.

City

Tehran

Province

Tehran

Postal code

1593749999

Phone

+98 21 8214 1229

Email

saki.ma@iums.ac.ir

2

Recruitment center

Name of recruitment center

Rasoul Akram Hospital, Tehran

Full name of responsible person

Naseh Yousefi

Street address

Firoozgar Hospital, Beh Afarin St, Valiasr Square

City

Tehran

Province

Tehran

Postal code

1593749999

Phone

+98 21 8214 1229

Email

saki.ma@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Seyed Abbas Motavlian

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614555

Phone

+98 21 8214 1229

Email

saki.ma@iums.ac.ir

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

Bijan Forgh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and Rehabilitation, Firoozgar Hospital, Beh Afarin Street, Valiasr Square

City

Tehran

Province

Tehran

Postal code

1449614555

Phone

+98 21 1229

Email

saki.ma@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Bijan Forgh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and Rehabilitation,
Firoozgar Hospital, Beh Afarin Street, Valiasr Square

City

Tehran

Province

Tehran

Postal code

1449614555

Phone

+98 21 8214 1229

Email

saki.ma@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahdieh Saki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Firoozgar hospital, behafarin street ,valiasr square

City

Tehran

Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Phone

+98 21 8214 1000

Fax

Email

saki.ma@iums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the patients data can be shared with privacy in regard to patients name

When the data will become available and for how long

Access period starts six months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of documents is allowed only by mentioning the source.

From where data/document is obtainable

Dr Bijan Forogh- Department of physical medicine and rehabilitation, Firoozgar Hospital, valiasr Square

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

Upon authenticated, the data is provided to the individual

Comments