Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, tumers, 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)

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+98 21 8214 1000

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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
۱۴۴۹۶۱۴۵۳۵
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.
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1593749999
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2

Recruitment center

Name of recruitment center
Rasoul Akram Hospital, Tehran
Full name of responsible person
Naseh Yousefi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr.Seyed Abbas Motavlian
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Iran University of Medical Sciences, Shahid Hemmat Highway
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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
Bijan Forgh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
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Person responsible for scientific inquiries

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Position
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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
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