

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

*Efficacy of transforaminal hyaluronidase versus transforaminal ozone in herniated lumbar disc pain

Protocol summary

Study aim

Efficacy of transforaminal hyaluronidase versus transforaminal ozone block in disc herniation lumbar pain

Design

This study is a double-blinded clinical trial with parallel control groups. The study is a pilot study and 45 patients in three groups have involved.

Settings and conduct

45 patients divided to three groups. Group TH received triamcinolone 20 mg, ropivacaine 0.2% 3cc, hyaluronidase 1500 units. Group TO received triamcinolone 20 mg, ropivacaine 0.2% and ozone 39 macro 5cc. Group TH received triamcinolone 20 mg, ropivacaine 0.2% 3cc, hyaluronidase 1500 units and ozone 39 macro 5cc. After transferring patients to the Rasool Akram hospital interventional pain procedure room, hydration achieved using normal saline 500cc. Patient was placed in a prone position. Local anesthesia was achieved by subcutaneous administration of 3cc lidocaine 1% injection. Then transforaminal lumbar epidural injection was done. The patients were then transferred to the pre-anesthesia care unit for monitoring vital signs, pain scores, and neurological adverse events. They were discharged home in the care of a responsible adult. Pain score (VAS), Oswestry disability index (ODI) and consumed-drugs measured after 2 weeks, 1 month, 2 months and 3 months.

Participants/Inclusion and exclusion criteria

Inclusions: radicular lumbar pain for more than 6 months, one or two involved levels, no response to conservative therapy for 3 months, pain score more than 3
Exclusions: patient discontent, ASA more than 2, spine deformity, spine fracture, anticoagulation therapy, drug and alcohol abuse, drug allergic reactions, local or systemic infection, pregnancy, MRI contraindications, severe pulmonary disease, severe psychiatric disease, peripheral neuropathy

Intervention groups

Groups divided to TH (hyaluronidase), TO (ozone) and

HO (hyaluronidase and ozone).

Main outcome variables

Consumed-drugs, Pain score, Oswestry disability index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181011041308N3**

Registration date: **2020-11-27, 1399/09/07**

Registration timing: **retrospective**

Last update: **2020-11-27, 1399/09/07**

Update count: **0**

Registration date

2020-11-27, 1399/09/07

Registrant information

Name

Mahmoud Reza Alebouyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 6136

Email address

alebouyeh.mr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
*Efficacy of transforaminal hyaluronidase versus transforaminal ozone in herniated lumbar disc pain

Public title
*Efficacy of transforaminal hyaluronidase versus transforaminal ozone in herniated lumbar disc pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Radicular lumbar pain for more than 6 months Disc protrusion One or two levels are involved No response to conservative therapy for 3 months Pain score more than 3
Exclusion criteria:
 Patient,s discontent ASA more than 2 Spine deformity Vertebral listhesis ,grade 2 or more Lumbar spine surgery Anti coagulation therapy Drug and alcohol abuse Drug allergic reactions Local or systemic infection Pregnancy MRI contraindications Severe pulmonary disease Severe psychiatric disease Peripheral neuropathy Spine fracture

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients randomly allocated into three groups. This study is a double-blind study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients and physicians don't have information about injected drugs.

Placebo
Not used

Assignment
Single

Other design features
45 patients suffering from radicular low back pain, allocated into tree groups.1_group TH received triamcinolone 20 mg,ropivacaine 0/2% 3cc,hyaluronidase 1500 units 2_group TO received triamcinolone 20

mg,ropivacaine 0/2% and ozone 39 macro 5cc3_group HO received triamcinolone 20 mg, ropivacaine 0/2% 3cc ,hyaluronidase 1500 units and ozone 39 macro 5cc. After transferring patients to the interventional pain procedure room, hydration achieved using normal saline 500cc .patient was placed in a prone position and the back was prepped .local anesthesia was achieved by subcutaneous administration of 3cc lidocaine 1% injection. Then transforaminal lumbar epidural injection was done. the patients were then transferred to the pre-anesthesia care unit for monitoring vital signs, pain scores and, neurological adverse events. They were then discharged home in the care of a responsible adult. Pain score (VAS), Oswestry disability index (ODI) and consumed- drugs, measured after 2 weeks, one month, 2months and 3 months.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.IUMS.FMD.REC.1399.424

Health conditions studied

1

Description of health condition studied

lumbar radicular pain

ICD-10 code

G54.1

ICD-10 code description

Lumbosacral plexus disorders

Primary outcomes

1

Description

Visual Analog Scale

Timepoint

2 weeks-1 month- 2 months-3 months

Method of measurement

asking from patient

2

Description

Oswestry Disability Index

Timepoint

2 weeks-1 month-2 months -3 months

Method of measurement

asking from patient

3

Description

consumed- drugs

Timepoint

2 weeks-1 month-2 months -3 months

Method of measurement

asking from patient

Secondary outcomes

empty

Intervention groups

1

Description

Control group: transforaminal hyaluronidase received triamcinolone 20 mg,ropivacaine 0/2% 3cc,hyaluronidase 1500 units

Category

Treatment - Drugs

2

Description

Intervention group: group TO:received triamcinolone 20 mg,ropivacaine 0/2% and ozone 39 macro 5cc3

Category

Treatment - Drugs

3

Description

Intervention group: received triamcinolone 20 mg, ropivacaine 0/2% 3cc ,hyaluronidase 1500 units and ozone 39 macro 5cc

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital pain clinic

Full name of responsible person

Dr Mahmoodreza Alebouyeh

Street address

Interventional operation room,Rasool Akram

hospital,Niyayesh street

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alebuieh.mr@iums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Abbas Motevallian

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Iran University of Medical Science -Hemmat highway- Tehran

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1458843337

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motevalian.a@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

Dr Mahmoodreza Alebouyeh

Position

Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

information about the main and secondary outcomes

When the data will become available and for how long

start the access period immediately after printing the results

To whom data/document is available

only individuals and academic institutions

Under which criteria data/document could be used

The result of any analysis without harmonization and permission is not published

From where data/document is obtainable

alebuieh.mr@iums.ac.ir

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

The request from the academic university will be answered within ten business days.

Comments