Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 tree groups have involved..

Settings and conduct
45 patients devided to tree 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, pine deformity spine fracture anticoagulation therapy, drug and alcohol abuse,drug allergic reactions, ocal or systemic infection pregnancy,MRI contraindications,severe pulmonary disease,severe psychiatric disease,peripheral neuropathy

Intervention groups
Groups devided 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)

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+98 21 2213 6136

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alebuieh.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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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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+98 21 8862 2552
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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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Interventional pain operation room,Rasool Akram hospital,Niyayesh street

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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