# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 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)

**Phone**
+98 21 2213 6136

**Email address**
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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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
**Street address**
Iran University of Medical Science -Hemmat highway- Tehran
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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 scientific inquiries

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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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**