

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effects of hyalase injection into hypertrophic ligamentum flovum on clinical symptoms and MRI findings in lumbar spinal canal stenosis

Protocol summary

Study aim

Evaluation of the effect of Hyalase injection into Hypertrophic Ligamentum Flovum on Clinical Symptoms and MRI findings in Lumbar Spinal Canal Stenosis

Design

Randomized, single-blinded, superiority, parallel-group trial on 40 randomly allocated patients into two equal groups (phase 3 study). Randomization will be performed via the Research Randomizer website.

Settings and conduct

A single blinded study on 40 patients at department of physical medicine and rehabilitation of Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients with chronic low back pain and claudication due to lumbar canal stenosis secondary to hypertrophy of ligamentum flovum with no response to conservative therapies with no history of laminectomy, coagulopathies and SOL in spinal cord

Intervention groups

Injection of 1 ml of 1500 Unites Hyalase and 40 mg of Methyl Prednisolone into the Ligamentum Flovum on group 1 and Transforminal injection of the same solution on group 2.

Main outcome variables

Chronic Low Back Pain, Neurologic complains, MRI findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110420006239N3**

Registration date: **2020-11-05, 1399/08/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-05, 1399/08/15**

Update count: **0**

Registration date

2020-11-05, 1399/08/15

Registrant information

Name

javad yazdani

Name of organization / entity

faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 41133559659

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yazdani@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-13, 1399/07/22

Expected recruitment end date

2020-12-15, 1399/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of hyalase injection into hypertrophic ligamentum flovum on clinical symptoms and MRI findings in lumbar spinal canal stenosis

Public title

Therapeutic effects of hyalase injection on lumbar spinal canal stenosis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Persistent Low Back Pain Lumbar Canal Stenosis
Hypertrophy of Ligamentum Flovum Inefficacy of
Conservative therapies Age over 18

Exclusion criteria:

Laminectomy Surgery Coagulopathy Dermal Infection
near the site of injection Presence of SOL in Spinal Cord
Ossification and Calcification Pregnancy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, block randomization will be used to achieve two groups with equal sample size. In order to randomize, first using the site <https://www.sealedenvelope.com/simple-randomiser/v1/lists> 40 codes (one code for each patient) in the form of two intervention groups with a sample size equal to the use of block sequences will be generated randomly. Each code will then be enclosed in a sealed envelope (40 envelopes in total) containing the study group information and will be kept confidential. At the time of patient admission, an envelope will be randomly assigned to each patient, and only at the time of the procedure will the physician in charge of the procedure have the right to open the envelope and view the procedure prescribed for that particular patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients will be kept unaware of which treatment group they have been assigned to. Furthermore, the data analyst will also be unaware of study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics committee of Tabriz University of medical sciences

Street address

No. 6, West Kahnamuyi Ave, North Shariati St, Valiasr Blvd

City

Tabriz

Province

East Azarbaijan

Postal code

5157683165

Approval date

2020-08-11, 1399/05/21

Ethics committee reference number

IR.TBZMED.REC.1399.500

Health conditions studied

1

Description of health condition studied

Lumbar Canal Stenosis secondary to Hypertrophic
Ligamentum Flovum

ICD-10 code

M48.06

ICD-10 code description

Spinal stenosis, lumbar region

Primary outcomes

1

Description

Pain intensity

Timepoint

Before injection and then one week after injection

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Imaging findings

Timepoint

Before injection and then one week after injection

Method of measurement

MRI findings due to Severity of Lumbar Canal Stenosis

Intervention groups

1

Description

Intervention group: a mixture of Hyalase 1500u and
40mg methylprednisolone injected into the ligamentum
flavum

Category

Treatment - Drugs

2

Description

Intervention group: a mixture of Hyalase 1500u and 40mg methylprednisolone injected via transforaminal rout at the level of the stenosis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dawood Aghamohammadi

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Imamreza Hospital, Golgasht St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpoor

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dawood Aghamohamadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the participants' data reported in the article relative to this trial after deidentification

When the data will become available and for how long

Immediately after publication regarding the publisher's policy

To whom data/document is available

Researchers who provide a methodologically sound proposal.

Under which criteria data/document could be used

Any purpose

From where data/document is obtainable

Dawood Aghamohamadi (daghamohamadi@yahoo.com) or Yalda Yazdani (yaldayznn@gmail.com)

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

Proposals should be directed to one of the above-mentioned email addresses. Requestors also will need to sign a data access agreement.

Comments