

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effects of laminectomy surgery on pain, functional disability, sensitivity of active trigger points in subjects with lumbar disc herniation

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

To determine and compare the mean pain, functional disability, sensitization and spinal myofascial pain syndrome in patients before and after lumbar laminectomy surgery and control groups.

Last update: **2019-06-21, 1398/03/31**

Update count: **0**

Registration date

2019-06-21, 1398/03/31

Design

Controlled clinical trial with parallel groups and double blinded

Registrant information

Name

Kamran Ezzati

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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kamranezzati@gums.ac.ir

Settings and conduct

This study will be performed at Poursina hospital. The study will be single blind and the examiner won't know the grouping and treatments procedures.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 30 to 60 years; L4L5 lumbar disc herniation diagnosis: According to neurosurgeon physician assessment and MRI findings. Non-inclusion criteria: The patients with fibromyalgia; subjects with surgical history of cervical, shoulder or other region of the body; Subjects with history of trigger point injection or acupuncture; Patients with laminectomy of other lumbar vertebrae or arthrodesis; Subjects with cauda equina syndrome which is reported by a neurosurgeon.

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Control group receive routine drug therapy treatments and are in waiting list for surgery and intervention group receive routine drug therapy as well as laminectomy surgery.

Main outcome variables

Pain, functional ability, sensitization and active trigger points

Scientific title

The effects of laminectomy surgery on pain, functional disability, sensitivity of active trigger points in subjects with lumbar disc herniation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N7**

Registration date: **2019-06-21, 1398/03/31**

Public title

The influence of laminectomy surgery on subjects with

lumbar disc herniation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30-60 years. L4-L5 Lumbar disc herniation diagnosis: According to neurosurgeon and magnetic resonance imaging(MRI) assessment.
Exclusion criteria:

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The examiner won't know anything about the kind of treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
5th floor, Central office of Guilan University of Medical Sciences, Namjoo St., Rasht, Iran

City
Rasht

Province
Guilan

Postal code
۴۱۹۳۷۱۳۱۹۴

Approval date
2018-01-16, 1396/10/26

Ethics committee reference number
IR.GUMS.REC.1396.344

Health conditions studied

1

Description of health condition studied
Lumbar disc herniation

ICD-10 code
M51.1

ICD-10 code description
Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description
Pain

Timepoint
Before and 1 month after surgery

Method of measurement
Visual Analogue Scale

2

Description
Functional disability

Timepoint
Before and 1 month after surgery

Method of measurement
Oswestry disability index

3

Description
Sensitization

Timepoint
Before and 1 month after surgery

Method of measurement
Pressure algometer

4

Description
Active trigger points

Timepoint
Before and 1 month after surgery

Method of measurement
manual evaluation

Secondary outcomes

empty

Intervention groups

1

Description
Control group: This group only receive anti-inflammatory drug therapy and are in waiting list for surgery or despite neurosurgeon recommendation don't want to operate for

any reason.

Category

Treatment - Surgery

2**Description**

Intervention group: In this group, lumbar laminectomy surgery is performed by a neurosurgeon. In order to release the nerve root and widening the lateral canal, the lamina is removed and the lateral canal is decompressed. After surgery, the target area is sutured and dressed and the patient is hospitalized up to 48 hours later.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Poursina hospital

Full name of responsible person

Kamran Ezzati

Street address

Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht

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4193731943

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Shadman Nemati

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Deputy of Research, in front of Azodi Stadium, Namjoo St, Rasht, Iran

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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

Guilan 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**

Guilan University of Medical Sciences, Deputy of Research

Full name of responsible person

Sosan Komaei

Position

Bachelor of science

Latest degree

Bachelor

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Kamran Ezzati

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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Email

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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

Sharing is done after the end of the study. The total potential data can be shared after unidentification of individuals.

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Researchers working at universities

Under which criteria data/document could be used

Researchers working in universities

From where data/document is obtainable

Address: Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht. Ez_kamran@yahoo.com

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

A written request for data from the relevant university with the name and academic degree of the researcher

Comments