Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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.

Design
Controlled clinical trial with parallel groups and double blinded

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.

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.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516034003N7**
Registration date: **2019-06-21, 1398/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-21, 1398/03/31**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

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

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

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

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9131293466

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Research@gums.ac.ir

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

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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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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 publicating 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
Adress: 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