Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

study of the clinical outcome of decompressive laminectomy surgery with and without fusion in patients with lumbar spinal stenosis

Protocol summary

Study aim
Comparison of the clinical outcome of decompressive laminectomy surgery with and without fusion in patients with lumbar spinal stenosis

Design
This study is a non-blinded clinical trial. The study population will be included all patients with lumbric canal stenosis refer to Imam Reza hospital of Kermanshah.126 eligible patients will be selected conveniently and randomly will be assigned to two intervention and control groups.

Settings and conduct
This study which will be conducted in Imam Reza hospital of Kermanshah city is non-blinded one. In this study, patients will be evaluated at the time of referring, 3 months and 9 months after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients suffering from lumbric canal stenosis that did not respond to medication

Intervention groups
In the intervention group, laminectomy surgery will be done with fusion. In the control group, a non-fusion laminectomy will be done

Main outcome variables
Patient's function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181122041726N1**
Registration date: **2018-12-23, 1397/10/02**
Registration timing: **prospective**

Last update: **2018-12-23, 1397/10/02**
Update count: **0**

Registration date
2018-12-23, 1397/10/02

Registrant information

Name
Saeed Gharooee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3262 2396

Email address
saeedgharooee@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-01, 1397/10/11

Expected recruitment end date
2019-01-31, 1397/11/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
study of the clinical outcome of decompressive laminectomy surgery with and without fusion in patients with lumbar spinal stenosis

Public title
study of the clinical outcome of decompressive laminectomy surgery with and without fusion in patients with spinal stenosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients suffering from lumbric canal stenosis that did

not respond to medication

Exclusion criteria:

Infection Congenital anomaly

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt. 126 similar cards will be provided which 63 of them are coded 1 which is indicative of the intervention group, and 63 of them are coded 2 which is indicative of the control group.Anyone who is eligible for inclusion in the study will selected one of these cards randomly (participants will not be aware of the type of intervention that they are assigned to).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

ir.kums.rec.1396.351

Health conditions studied

1

Description of health condition studied

Spinal canal stenosis

ICD-10 code

M48.06

ICD-10 code description

Spinal stenosis, lumbar region

Primary outcomes

1

Description

Patient's function

Timepoint

At the beginning of the study, 3 and 9 months after surgery

Method of measurement

Oswestry Disability Index (ODI)

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

In the intervention group, laminectomy surgery will be done with fusion.

Category

Treatment - Surgery

2

Description

In the control group, a non-fusion laminectomy will be done

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Saeid Gharooee Ahangar

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
Saied_gharooee@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3836 0014
Email
fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Saeid Gharooee Ahangar
Position
Resident of Neurological Surgery
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
Saied_gharooee@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Reza Fatahian
Position
Faculty Member of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
rfatahian@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Saeid Gharooee Ahangar
Position
Resident of Neurological Surgery
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province

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Postal code

6715847141

Phone

+98 83 3427 6306

Email

Saied_gharooee@yahoo.com

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

Not applicable

Title and more details about the data/document

If requested, results will be made available to other academic researchers

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments