

# 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

2018-12-23, 1397/10/02

#### 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 lumbar 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 lumbar 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

#### 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 lumbar 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  
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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  
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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  
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Emam Reza Hospital, Parastar Boulevard  
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## 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  
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## 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  
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Kermanshah  
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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**