

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Spinopelvic alignment in patients with lumbospinal stenosis and out come after simple decompression surgery

Protocol summary

Study aim

spinopelvic alignment in patients with lumbospinal stenosis and out come after simple decompression surgery

Design

Clinical trial without control group and evaluation of pre- and postoperative outcomes in patient group

Settings and conduct

At the beginning of the study, all patients with lumbar spinal stenosis referred to Imam Reza Clinic and candidate for decompression surgery after surgery were compared and compared with two surgical methods without consent and after obtaining consent form. Patients will be asked to complete VAS-index and back pain (VAS-Leg) questionnaires for VAS foot pain and ODI (Oswestry.Disability back) questionnaire, then undergo surgery by unilateral laminectomy and bilateral decompression by a surgeon. It will be performed with the same instrument (Crisson Punch No. 3.45) (and at Imam Reza Medical Complex) in Kermanshah

Participants/Inclusion and exclusion criteria

Patients with severe central canal stenosis who can be followed for 6 months and with coronary deformity less than 10° without severe foraminal stenosis who are stable on dynamic X-rays. Patients with coronary deformity based on SRS-Schwab classification, Patients with spondylolisthesis and Patients with spondylolysis will be excluded.

Intervention groups

In the selected group, surgery will be performed by unilateral laminectomy and bilateral decompression by a surgeon with the same instrument.

Main outcome variables

Pelvic Incidence, Pelvic Tilt, Sacral Slope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044145N1**

Registration date: **2019-11-02, 1398/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-02, 1398/08/11**

Update count: **0**

Registration date

2019-11-02, 1398/08/11

Registrant information

Name

Mohamad reza Akrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6475

Email address

mr_akrami@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Spinopelvic alignment in patients with lumbospinal stenosis and out come after simple decompression surgery

Public title

Spinopelvic alignment in patients with lumbospinal stenosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Severe central canal stricture Coronal deformity scoliosis lumbar Lack of instability dynamics in graphs Patients without severe foraminal stenosis

Exclusion criteria:

Patients with coronary deformity based on SRS-Schwab classification Patients with spondylolisthesis Patients with spondylolysis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 29

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Kermanshah University of Medical Science, Shahid Beheshti Boulevard, Kermanshah

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-03-19, 1397/12/28

Ethics committee reference number

IR.KUMS.REC.1397.1068

Health conditions studied

1

Description of health condition studied

lumbosacral stenosis

ICD-10 code

M48.07

ICD-10 code description

Spinal stenosis, lumbosacral region

Primary outcomes

1

Description

Spinopelvic alignment

Timepoint

Spinopelvic alignment will be measured at baseline (before surgery), first month, three month, and 6 month after surgery.

Method of measurement

In all patients, spine x-rays are performed from the T12 to the first 10 cm of the femoral head, with the hip and knee joint fully extended. ODI (Oswestry.Disability Index) and VAS-Leg (VAS-Leg) and VAS-Back (VAS-Back) questionnaires will also be completed for all patients.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Decompression surgery. The surgical procedure will be performed with unilateral laminectomy and bilateral decompression by a surgeon with the same tool (Crisson Punch 3.45 °) and in Imam Reza (AS) Kermanshah Therapeutic Complex. Patients will be ambulated the day after surgery and discharged without a brace on the third day of surgery. Patients will be allowed light daily activities on the day of discharge and allowed to remove heavy objects 3 months after surgery. Patients will be referred to the outpatient clinic at 1, 3, and 6 months after surgery by the same surgeon, and pelvic and lumbar radiographs in each Bat diseased repeated visits will be followed for 6 months.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Kermanshah

Full name of responsible person

Mohamad reza akrami

Street address

Imam Reza Hospital, Parastar Boulevard ,
Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6742775333

Phone

+98 83 3427 6300

Email

mr_akrami@kums.ac.ir

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

Street address

Imam Reza Hospital, Parastar Boulevard ,
Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6742775333

Phone

+98 83 3427 6300

Email

mr_akrami@kums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Kermanshah University of Medical Sciences, Shahid
Beheshti Boulevard, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

۶۷۱۴۶۷۳۱۵۹

Phone

+98 83 3837 0541

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

Mohamad reza akrami

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Mohamad reza akrami

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All potential data will be shared after people are unrecognizable.

When the data will become available and for how long

The access period will start 6 months after the results are published

To whom data/document is available

All academic researchers will have access to the data.

Under which criteria data/document could be used

The data will be available for new data analysis purposes.

From where data/document is obtainable

To access the study data corresponded author should be contacted. Mohammad Reza Akrami, Imam Reza Hospital, Parastar Boulevard , Kermanshah. Phone: 00988334276300. Email: mr_akrami@kums.ac.ir

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

Data will be shared after contacting the responder author and submission of the request, and after signing the data use agreement.

Comments