

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of clinical outcome of long-segment fusion spine surgery in degenerative scoliosis

Protocol summary

Study aim

Evaluation of clinical outcome of long-segment fusion spine surgery in degenerative scoliosis

Design

The present study is a semi-experimental per & after intervention. Patients underwent Long Fusion surgery, and the results of these surgeries are reviewed and recorded in the preoperative, immediate, and 6 months after surgery.

Settings and conduct

Patients who have referred to the spinal subspecialty clinic of Al-Zahra Hospital in Isfahan due to degenerative scoliosis and are candidates for surgery according to the treating physician

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with degenerative sclerosis
Obtaining written consent to participate in the study
Exclusion criteria: No patient visits for follow-up sessions, Dissatisfaction to enter or continue studying, Severe and malignant osteoporosis, Severe obesity, Inadequate medical conditions, Age over 70 years

Intervention groups

Patients underwent long fusion surgery and the results of this operation are checked and recorded in the pre-surgical, immediately after surgery, 3 and 6 months after the surgery.

Main outcome variables

Doing or not doing decompression and the number of decompression and fusion levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047079N1**

Registration date: **2020-05-20, 1399/02/31**

Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name

Soheil Fallahpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3624 7529

Email address

dr.sfallahpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-30, 1399/03/10

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical outcome of long-segment fusion spine surgery in degenerative scoliosis

Public title

clinical outcome of long-segment fusion spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with degenerative sclerosis Obtaining written

consent to participate in the study

Exclusion criteria:

No patient visits for follow-up sessions
Dissatisfaction to enter or continue studying
Severe and malignant osteoporosis
Severe obesity
Inadequate medical conditions
Age over 70 years

Age

To **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Street, Darvazeh-Shiraz Square

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-02-19, 1399/12/01

Ethics committee reference number

IR.MUI.MED.REC.1398.717

Health conditions studied

1

Description of health condition studied

Degenerative scoliosis

ICD-10 code

M41

ICD-10 code description

Scoliosis

Primary outcomes

1

Description

The severity of disability based on the ODI scale

Timepoint

In the preoperative period, immediately after surgery, 3 and 6 months after surgery are checked and recorded.

Method of measurement

Oswestry Disability Questionnaire (ODQ)

Secondary outcomes

empty

Intervention groups

1

Description

For patients with degenerative scoliosis, it is used in the long-segment fusion spine surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Subspecialty clinic of Al-Zahra Hospital in Isfahan

Full name of responsible person

Dr Soheil Fallahpour

Street address

Al-Zahra Medical and Educational Center, Al-Safa Boulevard,

City

Esfahan

Province

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Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

Web page address

<http://alzahra.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoe Javanmard

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,
Shiraz Gate,

City

Isfahan

Province

Isfahan

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۷۳۴۶۱-۸۱۷۴۶

Phone

+98 31 3668 0048

Email

alzahra@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

1

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Majid Rezvani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Majid Rezvani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Soheil Fallahpour

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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

A part of the data such as information about the main consequence
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Researchers working in academic institutions
From where data/document is obtainable
dr.sfallahpour@gmail.com
What processes are involved for a request to access data/document
One month after receiving the email
Comments