

# 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**

Isfahan

**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

**Postal code**

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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Al-Zahra Educational and Medical Center, Al-Safa  
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## Person responsible for scientific inquiries

**Contact**

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Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

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**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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**Email**

dr.sfallahpour@gmail.com

## 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**