Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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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

Isfehan

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,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
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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 updating data

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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