Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of the sagittal insertion angle of pedicle screws on postoperative thoracic kyphosis in adolescent idiopathic scoliosis.

Protocol summary

Study aim
The Effect of the Sagittal Insertion Angle of Pedicle Screws on Postoperative Thoracic Kyphosis in Adolescent Idiopathic Scoliosis

Design
A clinical trial with two groups of parallel, randomized intervention will be performed using random allocation software.

Settings and conduct
The angles of scoliosis, kyphosis, and vertebrae will be recorded, and patients will undergo posterior spinal fusion correction surgery with posterior spinal fusion using all-inclined and inclined pedicle screws. 1st, 12th, and 60th months in postoperative follow-up, scoliosis and kyphosis angles, and the vertebrae will be re-registered. By comparing the two groups, the best angle of placement of the pedicular screws of the thoracic vertebrae, and its effect on the angle of the thoracic kyphosis after idiopathic correction surgery in adolescents will be determined. Study place: Mofid and Taleghani Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with idiopathic adolescent scoliosis. Exclusion criteria: Patients with neuromuscular and congenital scoliosis.

Intervention groups
1st intervention group: Patients will be operated on in the form of oblique pedicle screws 2nd intervention group: Patients will be operated on in the form of Parallel pedicle screws

Main outcome variables
Comparison of the effect of the sagittal Insertion angle of pedicle screws on postoperative Thoracic Kyphosis in adolescent idiopathic scoliosis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211218053441N1**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **retrospective**

Last update: **2022-02-06, 1400/11/17**
Update count: **0**

Registration date
2022-02-06, 1400/11/17

Registrant information

Name
Mohsen Karami

Name of organization / entity

Country
Iran (Islamic Republic of)

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mkarami@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-04-21, 1393/02/01

Expected recruitment end date
2016-03-22, 1395/01/03

Actual recruitment start date
2016-03-22, 1395/01/03

Actual recruitment end date
2016-03-22, 1395/01/03

Trial completion date
2017-12-20, 1396/09/29

Scientific title
The effect of the sagittal insertion angle of pedicle screws on postoperative thoracic kyphosis in adolescent idiopathic scoliosis.

Public title
The effect of the sagittal insertion angle of pedicle screws on postoperative thoracic kyphosis in adolescent idiopathic scoliosis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with idiopathic adolescent scoliosis
Exclusion criteria:
Patients with neuromuscular and congenital scoliosis.
Age
From **10 years** old to **19 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **18**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization for 2 intervention groups. The randomization method will be done using software, 10 random numbers for each intervention group. The researcher can not play a role in predicting treatment of the disease, and choosing the type of surgery. Random sequence will generate by software. Group 1: 10 Cases and Group 2: 10 cases. Admitted patients will be placed in one of two groups according to the pre-determined code.
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
Research Institute for Children Health - Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Arabi st, Velenjak st, Tehran
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2021-12-20, 1400/09/29
Ethics committee reference number
IR.SBMU.RICH.REC.1400.057

Health conditions studied

1

Description of health condition studied
Adolescent Idiopathic Scoliosis
ICD-10 code
M41.1
ICD-10 code description
Juvenile and adolescent idiopathic scoliosis

Primary outcomes

1

Description
Comparison of the effect of the sagittal Insertion angle of pedicle screws on postoperative Thoracic Kyphosis in adolescent idiopathic scoliosis.
Timepoint
1st, 12th, and 60th months in postoperative follow-up.
Method of measurement
The measurement is done from x-ray by Surgimap software.

Secondary outcomes

1

Description
Comparison of the effect of the sagittal Insertion angle of pedicle screws on postoperativelumbar lordosis angle.
Timepoint
1st, 12th, and 60th months months in postoperative follow-up.
Method of measurement
The measurement is done from x-ray by Surgimap software.

2

Description
Comparison of the effect of the sagittal Insertion angle of pedicle screws on postoperative main Thoracic curve angle.
Timepoint
1st, 12th, and 60th months in postoperative follow-up.
Method of measurement
The measurement is done from x-ray by Surgimap software.

3

Description
Comparison of the effect of the sagittal Insertion angle of

pedicle screws on postoperative main Cobb’s angles.

Timepoint

1st, 12th, and 60th months in postoperative follow-up.

Method of measurement

The measurement is done from x-ray by Surgimap software.

Intervention groups

1

Description

Intervention group: Patients will be operated on in the form of oblique pedicle screws

Category

Treatment - Surgery

2

Description

Intervention group: Intervention group: Patients will be operated on in the form of Parallel pedicle screws

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid children's Hospital

Full name of responsible person
Dr Mohsen Karami

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Shariati st

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Tehran

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1551415468

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2

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Dr Mohsen Karami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Vice Chancellor for research and technology, Shahid Beheshti University of Medical Sciences

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for research and technology, Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Mohsen Karami

Position
Associate professor

Latest degree
Subspecialist
Other areas of specialty/work
Spine surgery
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
Data can be shared potentially after patients became unrecognizable.
When the data will become available and for how long
After completing the results and analyzing the data, access to them is allowed.
To whom data/document is available
This will be available for people working in academic institutions
Under which criteria data/document could be used
After obtaining written permission, the use of the data is permitted with reference to the source.
From where data/document is obtainable
Dr Mohsen Karami: mn.karami@gmail.com
What processes are involved for a request to access data/document
After completing the results and analyzing the data, the use of the data is allowed after the written request.
Comments