

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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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+98 21 2243 2560

Email address

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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2

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

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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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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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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