

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of accuracy and cost-effectiveness of using surgical guidance system with the help of fluoroscopic images in placing pedicle screws in comparison with conventional methods

Protocol summary

Study aim

Determining the relationship of project variables in pedicle screw operation using navigation based on C-arm imaging in comparison with conventional free-hand surgery

Design

The study will be performed in two groups of control and intervention group as double blinded and randomized through random numbers using Excel. The sample size in this study is 44 patients.

Settings and conduct

This clinical trial project is being carried out using the C-Guide system, a product of Parsis Company and performed in Shariati Hospital. This study is double blinded in which patients and the person in charge of data analysis are not aware. In Parsis surgical guidance system, images are analyzed and calibration processes are performed. The doctor will then be able to see the direction of his instrument on the images.

Participants/Inclusion and exclusion criteria

The subjects are patients who have to undergo spine surgery and pedicle screw implantation in the neck, chest, lumbar and sacral surfaces. Exclusion criteria are as follows: Dissatisfaction with participation in the study and age under 18 years

Intervention groups

There are patients who will have pedicle screw implantation using Surgical navigation or Fluoroscopy.

Main outcome variables

Method of intervention (embedding pedicle screws)
Duration of screw installation
Duration of operation
Received radiation
Total radiation time
Number of repeating radiography
Number of drills
Investigation of the position of screws and the amount of cortical perforations and pedicle wall violation by imaging
Duration of presence in the operating room
Setup time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051854N4**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

Registration date

2022-11-05, 1401/08/14

Registrant information

Name

Mohammad Hossein Nabian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 1444

Email address

dr.nabian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of accuracy and cost-effectiveness of using surgical guidance system with the help of fluoroscopic images in placing pedicle screws in comparison with conventional methods

Public title

Evaluation of the effect of surgical guidance system in spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have spinal surgery and a pedicle screw implanted in the neck surface. Patients should have spinal surgery and a pedicle screw implanted in the chest surfaces. Patients should have spinal surgery and pedicle screw implantation in the lumbar surfaces. Patients should have spinal surgery and pedicle screw implantation at the sacral surfaces.

Exclusion criteria:

Dissatisfaction with participating in the study Age under 18 years

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into control and intervention groups. The randomization of people will be done using the Permuted block randomization method with the random selection of the size of the blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding method in this study is double blinded in which patients and the person responsible for data analysis are not aware of the randomization setting of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-
Tehran University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical
Education Headquarters, Between Zarafashan &
South Falamak, Qods Town

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1304

Health conditions studied

1

Description of health condition studied

Spine surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Screw insertion time

Timepoint

From the time of the start of the distal screw insertion
until the end of it, during the operation

Method of measurement

Based on the time measured by the stopwatch

2

Description

Duration of operation

Timepoint

From the time of the first fluoroscopic image of the organ
to the time of preparing the fluoroscopic image for the
final check

Method of measurement

Based on the time measured by the stopwatch

3

Description

Radiation dose received

Timepoint

The amount of radiation received during the operation

Method of measurement

With the help of special radiology badges

4

Description

X-ray radiation time

Timepoint

The duration of taking pictures with the C arm in each of the imaging methods

Method of measurement

Using the device's own settings

5

Description

The number of repetitions of photography

Timepoint

The number of times of taking pictures with the arm in each of the imaging methods

Method of measurement

Using the device's own settings

6

Description

Duration of operating room stay

Timepoint

The duration of the patient's presence in the operation room from the time of entry to the time of exit

Method of measurement

Based on the time measured by the stopwatch

7

Description

Setup time

Timepoint

The time required to set up the operation equipment

Method of measurement

Based on the time measured by the stopwatch

Secondary outcomes

1

Description

Checking the alignment of screws by imaging

Timepoint

Checking the alignment of the distal screws with respect to the contour in the post-operative graph - the presence or absence of angulation and torsion

Method of measurement

Based on the opinion of an orthopedic and radiology specialist

Intervention groups

1

Description

Intervention group: There are patients who will have pedicle screw implantation using Surgical navigation or Fluoroscopy.

Category

Treatment - Other

2

Description

Control group: Includes patients in whom the placement of the pedicle screw will be determined using the conventional method (conventional C-arm).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mohammad Hossein Nabian

Street address

North Kargar St., Jalal Al-Ahmad Three Ways, Opposite the Faculty of Economics, Dr. Shariati Research and Treatment Center

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

+98 21 8863 3039

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Parseh Intelligent Surgical Systems Co.

Full name of responsible person

Mustafa Abdul Ghafar

Street address

No. 8, Hamedan Aly, North Kargar St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1418693914

Phone

+98 21 4066 0365

Fax

+98 21 6612 4395

Email

contact@parsiss.com

Grant name

Grant code / Reference number

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

Yes
Title of funding source
Parseh Intelligent Surgical Systems Co.
Proportion provided by this source
85
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

2

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Vice Chancellor for Research and Technology, Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

15

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Nabian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

mh-nabian@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Nabian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

mh-nabian@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Nabian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City

Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
mh-nabian@sina.tums.ac.ir

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

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

Yes - There is 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

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

After printing the results as an article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For further research purposes and analysis

From where data/document is obtainable

In order to receive the data, it is necessary to refer to the scientific accountant or the corresponding author of the article

What processes are involved for a request to access data/document

An official letter or e-mail

Comments