

# 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**

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## **Person responsible for updating data**

### **Contact**

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Tehran University of Medical Sciences

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Dr. Mohammad Hossein Nabian

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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**