Handheld iOS-based spinal navigation versus computer tomography-based image guided navigation in the placement of thoracolumbar pedicle screws; protocol of a randomized controlled trial

Published: 25-05-2021
Last updated: 19-08-2024

The aim of the study is to determine the accuracy of pedicle screw placement when using the iNav navigation tool compared with the established computertomography based navigation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON55222

Source
ToetsingOnline

Brief title
iNav navigation study

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
spondylolisthesis, vertebral slippage

Research involving
Human

Sponsors and support

Primary sponsor: Circinus Medical Technology
Source(s) of monetary or material Support: Circinus Medical Technology

Intervention

Keyword: fusion, instrumentation, navigation, pedicle screw

Outcome measures

Primary outcome

The main endpoint is the accuracy of the pedicle screw position according to

the classification of Gertzbein and Robbins in which Grade A and B are defined

as *good position*, based on the computertomography imaging at the end of each

surgical procedure.

Secondary outcome

Other study parameters are duration of surgery, complications, and length of

hospital stay.

Study description

Background summary

Spinal instrumentation is more frequently performed with the aid of navigation resulting in good outcome and less complications. Since the established computer tomography-based navigation system is costly and associated with radiation exposure, there is a need for alternative less complex navigation systems with similar accuracy. Recently, a novel iOS (operating system on which Apple personal devices run) based spinal navigation system has been developed; iNav system (Circinus Medical Technology).

Study objective

The aim of the study is to determine the accuracy of pedicle screw placement when using the iNav navigation tool compared with the established computertomography based navigation.

Study design

The research project will start with a pilot study on 20 patients who will be operated with iNav navigation, which will be compared and checked with the standard computertomography based navigation during surgery. Whenever at least 90% of the implanted pedicle screws have an acceptable position in the pedicle, we will continue with the randomized trial, which is designed as a randomized controlled single-blinded, single center, non-inferiority trial in which iNav navigation will be compared with computertomography based navigation.

Intervention

Patients undergoing spinal navigated instrumentation will be randomized into one group in which pedicle screws will be inserted by guidance of the iNav system, and one group in which pedicle screw will be inserted by guidance of the computertomography based navigation.

Study burden and risks

The patients will not experience any burden since the study objective concerns the surgical navigation procedure only, and no additional imaging, blood sample, nor questionnaires will be asked. In general, pedicle screw fixation can be associated with a small risk of screw malposition with consequent nerve root injury. In case of iNav navigation, the risk of pedicle screw deviation might be higher although all patients will receive intraoperative computertomography control imaging to check the iNav pedicle trajectory and reposition the screw if necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients older than 18 years
- informed consent
- single or multilevel fusions (T12 to S1) for the following indications:
degenerative spinal stenosis
spondylolisthesis
degenerative disc disease
failed back surgery syndrome.

Exclusion criteria

- cervical surgery and thoracic surgery above T12.
- trauma, infection, and tumor.
- cortical trajectory screw fixation.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2022
Enrollment:	167
Type:	Actual

Medical products/devices used

Generic name:	iOS navigation device (iNav)
Registration:	No

Ethics review

Approved WMO

Date:	25-05-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-02-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-03-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74268.058.20