Prospective clinical study with Surgical Navigation Release 1.5 and Bone Access Trackable Needle to plan, position and check instrument placement for percutaneous spine surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24700

Source
NTR

Brief title
TBA

Health condition

spondylolisthesis, spondylolysis, stenosis, fractures, tumors, disc herniation

Sponsors and support

Primary sponsor: Philips Medical Systems Nederland B.V.
Source(s) of monetary or material Support: Philips Medical Systems Nederland B.V.

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study is the determination of thoracolumbar sacral pedicle screw placement accuracy.

Secondary outcome

-Average time required for complete surgical procedure (skin incision to skin closure)
-Average time to place screw in optimum position.
-Patient dose
-Operator radiation dose
-User feedback on workflow usability
-Adverse events
-Adverse device effects
-Device deficiencies that could have led to a serious adverse event
-Comparison of obtained accuracy with accuracy data from the pre-clinical cadaver study

Study description

Background summary

There is a clear need in spine surgery to place pedicle screws in the right place in the spine with good accuracy to avoid damage to important structures (i.e. spinal cord, nerve roots or vertebral arteries). The objective of the study is to investigate the accuracy of screw placement during minimally invasive spine surgery.

Study objective

No formal statistical hypothesis is planned

Study design

Subjects will be followed-up from start of the interventional procedure until hospital discharge.
The total duration of the study is expected to take approximately 12 months.

Contacts

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Eligibility criteria

Inclusion criteria

-Subject will be undergoing a percutaneous spine surgery with thoracolumbar sacral pedicle screw placement in a maximum of 4 levels to stabilize the spine for spine pathologies like spondylolisthesis, spondylolysis, stenosis, fractures, tumors, disc herniation.
-Subject is able to give informed consent and is 18 years of age or older, or of legal age to give informed consent per state or national law

Exclusion criteria

-Subject participates in a potentially confounding drug- or device trial during the course of the study.
-All vulnerable subjects such as adults lacking the capacity to provide consent, patients in emergency situations, pregnant or breast feeding women, or any other subject who meets an exclusion criteria, according to applicable national laws, if any
-All subjects who are employees of the parties involved in the study
-The distance between the skin entry point and the position of the Bone access needle tip inside the pedicle should not exceed 108 mm as this may obscure the tracking marker on the needle shaft, potentially causing failure of device tracking functionality.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2019
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	13-08-2019
Application type:	First submission

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
NTR-new	NL7956
Other	SwissMedic (Lugano), Medizinische Fakultät Der Christian-Albrechts-Universität Zu Kiel (Kiel) : SwissMedic: 102607492, Medizinische Fakultät Der Christian-Albrechts-Universität Zu Kiel: 00011811

Study results