Post-operative outcomes of pain management in spinal fusion surgery

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Most patients undergoing spine surgery with pedicle screw instrumentation will experience insufficient pain relief in the first three days after surgery, whereafter postoperative pain can be managed with conventional, non-opioid analgesics in most...

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON23831

Source
Nationaal Trial Register

Brief title
STX-102

Condition

- Nervous system, skull and spine therapeutic procedures

Health condition

Various spinal pathologies requiring surgical stabilization

Research involving
Human

Sponsors and support

Primary sponsor: SentryX
Source(s) of monetary or material Support: SentryX

Intervention

- Surigical procedure

Explanation

Outcome measures

Primary outcome

Pain, opioid usage and mobilization

Secondary outcome

Medicine use, side-effects, adverse events, length of stay in the hospital, discharge destination, and patient satisfaction

Study description

Background summary

Pain management after musculoskeletal surgery remains a major challenge. Despite 95% of patients receiving systemic opioids, which are associated with many toxic side effects and are highly addictive, inadequate pain is still reported in up to 80% of patients. The current study aims to quantify the incidence of insufficient pain relief after instrumented spine surgery and to analyse the relationship between postoperative pain, opioid consumption and mobilization.

Study objective

Most patients undergoing spine surgery with pedicle screw instrumentation will experience insufficient pain relief in the first three days after surgery, whereafter postoperative pain can be managed with conventional, non-opioid analgesics in most cases.

Study design

Up to 10 days postoperatively

Intervention

Spinal instrumentation using pedicle screws

Contacts

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Eligibility criteria

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

Inclusion criteria

- Males and females aged 18 years and older - Planned for open or percutaneous* posterior instrumentation with a minimum of 4 new pedicle screws with a diameter of 5 to 7,5 mm (inclusive). - Concomitant posterolateral fusion, vertebral augmentation, intervertebral body fusion devices, osteotomies and posterior decompression are acceptable - Willing and able to comply with the protocol for the duration of the study - Give written informed consent prior to any study-related procedure not part of the standard practice, with the understanding that the consent may be withdrawn by the patient at any time without prejudice to his/her (post-)surgery care

Exclusion criteria

- Concomitant anterior/lateral procedures (e.g. vertebral cage, anterior plating, ALIF/XLIF) - ASA-classification > 3 - Disrupted pain perception according to the treating physician - High risk of intra-/postoperative complications (e.g. multiple prior procedures) - Indication for surgery being: Active or previous (para)spinal infection; Malignancy; Fracture/other traumatic injury; Indication for an epidural catheter; Indication for local infiltration analgesics with amino-amide anesthetics; Known intolerance to patch adhesives; Participation in an interventional study interfering with standard care

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2022
Enrollment:	66
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	28-05-2021
Application type:	First submission
Review commission:	Stichting Beoordeling Ethiek Biomedisch Onderzoek Dr. Nassaulaan 10 9401 HK Assen 059 2405871 info@stbebo.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
NTR-new	NL9703
Other	Dutch Clinical Research Foundation : NWMO21.05.022

Study results