A Neurosurgical Aspirin Intervention Study

Published: 15-10-2020
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The aim of this study is to investigate the non-inferiority of perioperative continuation of aspirin patients undergoing spinal surgery, compared with the current policy of perioperative discontinuation of aspirin.

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

Summary

ID

NL-OMON20747

Source
Nationaal Trial Register

Brief title
Aspin

Health condition

Post-operative hemorrhagic complications and thrombo-embolic complications after neurosurgical spinal surgeries in patients using aspirin anti-thrombotic medication.

Sponsors and support

Primary sponsor: Haaglanden medical center.
Source(s) of monetary or material Support: HMC Wetenschapsfonds

Intervention

Outcome measures

Primary outcome

Primay outcome measures include perioperative blood loss, hemorrhage related complications and need for reoperation.

Secondary outcome

Secondary outcome is the reduction of cardiac and neurologic thrombotic perioperative events within 30 days after surgery.

Study description

Background summary

Aspirin is typically discontinued in cranial and spinal surgery because of increased risk of hemorrhagic complications, but comes together with the risk of resulting in an increase of cardiac and neurologic thrombotic perioperative events.

Study objective

The aim of this study is to investigate the non-inferiority of perioperative continuation of aspirin patients undergoing spinal surgery, compared with the current policy of perioperative discontinuation of aspirin.

Study design

Pre-operative assessment: informed consent, inclusion and randomisation. Direct post-operative assessment: operative blood loss (suction system and gauzes), first day blood loss in subcutaneous drain, level of mobilisation, days of clinical admission, level of pain. Outpatient clinic check up: woundinspection (infection, wound recovery), thrombo-embolic complications (neuro-vascular/cardiologic).

Intervention

Current practice guidelines recommend the discontinuation of aspirin 5 days pre-operatively until at least 3 days post-operatively. The intervention in the Aspin-study is to observe the rate of hemorhaghic complictions in patients undergoing spinal neurosurgery that continue the intake of aspirin peri-operatively, which is the intervention group.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: • Scheduled spinal surgery • Preoperative use of aspirin • Age >18

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: • Surgery with high risk for hemorrhage such as tumors requiring preoperative embolization • Staged surgeries lasting more than one day • Patients with a pre-existing coagulopathy • Patients using antithrombotic drugs or other platelet aggregation inhibitors than aspirin • Patients with absolute contraindication for discontinuing aspirin (e.g. coronary stenting within 1 year) • Patients aged under 18 • Emergency surgical procedures

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-01-2022
Enrollment:	554
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54741
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8986
Other	METC Leiden Den Haag Delft : P14.296 METC LDD
CCMO	NL71200.058.20
OMON	NL-OMON54741

Study results