A Neurosurgical Aspirin Intervention Study

Gepubliceerd: 15-10-2020 Laatst bijgewerkt: 13-01-2025

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20747

Bron
Nationaal Trial Register

Verkorte titel
Aspin

Aandoening

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

Ondersteuning

Primaire sponsor: Haaglanden medical center.
Overige ondersteuning: HMC Wetenschapsfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primay outcome measures include perioperative blood loss, hemorrhage related

complications and need for reoperation.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Haaglanden medisch centrum, afdeling Neurochirurgie
Ahmed Zian

0634127515

Wetenschappelijk

Haaglanden medisch centrum, afdeling Neurochirurgie
Ahmed Zian

0634127515

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-01-2022
Aantal proefpersonen:	554
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54741
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8986
Ander register	METC Leiden Den Haag Delft : P14.296 METC LDD

Register	ID
CCMO	NL71200.058.20
OMON	NL-OMON54741

Resultaten