Prospective analysis of predictive risk factors of Postoperative Intestinal Ischemia after Abdominal Aortic Aneurysm surgery

Gepubliceerd: 27-09-2019 Laatst bijgewerkt: 18-08-2022

The model will help reduce the mortality associated withintestinal ischaemia as a complication of AAA surgery.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26644

Bron
Nationaal Trial Register

Verkorte titel
PORSCHE

Aandoening

Abdominal aortic aneurysm; intestinal ischaemia

Ondersteuning

Primaire sponsor: Stichting Haga Vascular Research
Overige ondersteuning: Stichting Haga Vascular Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

o To assess if our model is accurate in the prediction of postoperative intestinal ischemia.
 High predictive scores in patients who develop clinical signs of intestinal ischemia
 Higher/rising serum D-dimer, procalcitonin and IFABP levels in patients who develop clinical signs of intestinal ischemia
o The practicability and feasibility of the model in the clinical practice
 Usefulness according to vascular surgeons
o Postoperative mortality based on intestinal ischemia
 Mortality in study population compared to usual postoperative mortality numbers

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Intestinal ischemia is a rare, yet dreaded complication after surgical repair of an abdominal aortic aneurysm (AAA).
Objective: The main objective is to assess if our model, consisting of patient-related and procedure-related factors, complemented/together with measurements of serum D-dimer, procalcitonin and IFABP levels is accurate in the prediction of postoperative intestinal ischemia in patients undergoing both elective and acute aneurysm surgery.
Study design: Prospective observational cohort study
Study population: Patients of the Haga Hospital in which surgery of an abdominal aortic aneurysm should take place, 18-90 years old.
Main study parameters/endpoints:
- To assess if our model is accurate in the prediction of postoperative intestinal ischemia.
o High predictive scores in patients who develop clinical signs of intestinal ischemia
o Higher/rising serum D-dimer, procalcitonin and IFABP levels in patients who develop clinical signs of intestinal ischemia
- The practicability and feasibility of the model in the clinical practice
- Postoperative mortality based on intestinal ischemia
Secondary study parameters/endpoints: Prolonged length of hospital stay
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Extra blood samples will be taken, a maximum of 2-3 times. The estimated risk associated with venapuncture is low.

Doel van het onderzoek

The model will help reduce the mortality associated withintestinal ischaemia as a complication of AAA surgery.

Onderzoeksopzet

Preparation

Onderzoeksproduct en/of interventie

AAA repair, open and endovascular

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult patient, from eighteen up to ninety years old with an abdominal aortic aneurysm, admitted to the hospital for surgical correction of the aneurysm.
- Atherosclerotic aethiology of the AAA

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Aethiology other than atherosclerotic disease
- Age ninety years or above
- Patients unable to give informed consent
- Patients with a history of intestinal ischemia
- Patients with active malignancies

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	27-09-2019
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8053
CCMO	NL70817.098.19

Resultaten