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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26644

Source
Nationaal Trial Register

Brief title
PORSCHE

Health condition

Abdominal aortic aneurysm; intestinal ischaemia

Sponsors and support

Primary sponsor: Stichting Haga Vascular Research
Source(s) of monetary or material Support: Stichting Haga Vascular Research

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Prolonged length of hospital stay

Study description

Background summary

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.

Study objective

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

Study design

Preparation

Intervention

AAA repair, open and endovascular

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-09-2019
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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	NL8053
CCMO	NL70817.098.19

Study results