Comparative study on the Inflammatory Response after Endovascular Aortic aneurysm Repair and Endovascular Aneurysm Sealing

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Primary objectiveTo establish whether EVAS results in a reduced post-operative inflammatory response , reflected by a lower incidence of the post-implant syndrome, during the first year after surgery, compared to EVAR as assessed by trends in...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON46674

Source
ToetsingOnline

Brief title
INSPIRE study

Condition

- Aneurysms and artery dissections

Synonym
Inflammatory response

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: Endologix

Intervention

Keyword: Aortic aneurysm, EVAR, EVAS, Post Implant Syndrome

Outcome measures

Primary outcome

The difference in early post-operative and long term inflammatory response between EVAS and EVAR, measured by the incidence of the post-implant syndrome, the rise in WBC and circulating cytokines (TNF-*, Interleukin (IL)-1, 1RA, 6, 10, 18, CRP), Troponin I, NT-pro-BNP, at specified time points up to 12 months after surgery.

Secondary outcome

1. The change in aortic thrombus volume and its relationship with the inflammatory response, measured by cytokines* concentrations.

2. Post-operative pyrexia, measured at 24 and 48 hours.

3. 30-day and 1-year morbidity, cardiac complications (including measures of troponin I, NT-proBNP, and (all-cause and cardiac) mortality, their relationship with the type of graft used and the inflammatory response, measured by cytokines* concentrations.

Study description

Background summary

Endovascular sealing of abdominal aortic aneurysms (EVAS) is a new technique to treat infrarenal abdominal aortic aneurysms (AAA), which can be performed more expeditiously than endovascular aneurysm repair (EVAR). The difference with EVAR is that fixation and seal are provided from polymer filled endobags that

are placed in the aneurysmal sac. The post-implantation syndrome (PIS) is the clinical and biochemical expression of an inflammatory response following endovascular repair of an aortic aneurysm. More specifically, the presence of fever (body temperature >38 C for *1 day) and leukocytosis (WBC >12.000/mL) with negative blood cultures and is occurring in over 30% cases after EVAR. It is related to prolonged hospital stay and elevated CRP levels, that in turn increase the risk on major adverse cardiac events. The presence of PIS is an independent predictor of an adverse event during the first 30 days. Sartipy et all (2015) showed that the magnitude of the post-operative inflammatory response depends on the type of endoprosthesis used for EVAR. Anecdotal reports suggest that EVAS causes a dampened inflammatory response compared to EVAR. Berg et all (2017) recently showed that EVAS is related to a lower postoperative CRP level, lower white blood counts and a lower temperature, compared to standard EVAR. In addition, less cardiac complications were seen. This difference may be due to many factors, including the avoidance of fresh luminal thrombosis after EVAS (as the endobags completely fill the aneurysm flow lumen) and/or the different physical properties of the endograft. If confirmed, this may result in improved clinical outcome, as the magnitude of the post-operative inflammatory response has been correlated with the occurrence of complications. The one-year data of the EVAS-FORWARD Global showed a higher than expected freedom from all-cause mortality rate (95%), mainly driven by a 98% freedom from cardiovascular death. The current study was designed to compare the occurrence of the post-implantation syndrome after EVAR and EVAS of people aged 50 years and older since aneurysms that occur at young age are mostly inflammatory. This study was also designed to unravel the cytokines which are involved in the post-implantation syndrome after EVAR and EVAS.

Study objective

Primary objective
To establish whether EVAS results in a reduced post-operative inflammatory response , reflected by a lower incidence of the post-implant syndrome, during the first year after surgery, compared to EVAR as assessed by trends in circulating inflammatory cytokine concentration.

Secondary objectives
1. To establish if there is a difference in the incidence of the Post Implant Syndrome between EVAR and EVAS.
2. To establish whether the post-operative inflammatory response after EVAR/EVAS is proportional to changes in aortic intra-luminal thrombus.
3. To investigate the relationship between the measured post-implant inflammatory response and cardiac damage as measured by troponin and Pro-BNP and cardiac adverse events.

Study design

A prospective observational comparative study.

Study burden and risks

Abdominal Aortic Aneurysm is a life threatening condition. Although treatment of these aneurysms with endovascular devices is generally safe, intra-operative and post-operative complications can and do occur. In this observational study all surgical or medical procedures will performed per standard of care at each participating Institute. The study protocol itself does not therefore introduce any additional risk for the patient.
Patients treated with endovascular devices are generally monitored on an annual basis to detect device related complications or disease expansion, with a more intense surveillance during the first year. This study protocol will collect routine clinical data at specified time points and will not require additional patient visits or investigations, except for the blood sampling which is mandatory.
There are no direct harms or benefits to an individual patient associated with participation in this study. However, collectively the data generated by this study will benefit the medical and surgical communities* understanding of the performance of the studied devices.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Elective EVAR/EVAS
- Ability and willingness to provide written informed consent
- Age *50 years

Exclusion criteria

- Complex EVAR or EVAS, including iliac branched and supra-renal repairs (pre-planned visceral chimneys, fenestrations or branches)
- Ruptured or symptomatic AAA
- Planned internal iliac artery embolization
- Acute or chronic inflammatory illness (i.e. upper respiratory tract infection)
- Active rheumatoid arthritis
- Inflammatory bowel disease
- Inflammatory and mycotic aneurysms
- Planned associated surgical procedure (i.e. iliac conduit, femoral endarterectomy, etc.)
- Previous aortic surgery (open or endovascular)
- Untreated malignancy
- Major surgery six weeks before EVAR/EVAS
- Ongoing or recent immunosuppressive treatment, including corticosteroid use

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	22-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL64578.091.18