Clinical relevance of Positron Emission Tomography (PET) imaging following endovascular aneurysm repair using the Nellix endoprosthesis.

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To determine FDG uptake following uncomplicated EVAR using the Nellix endoprosthesis. Does uncomplicated EVAR using the Nellix endoprosthesis result in increased FDG uptake and false positive PET imaging? .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

Summary

ID

NL-OMON40667

Source
ToetsingOnline

Brief title
PET imaging following endovascular aneurysm repair

Condition

- Aneurysms and artery dissections

Synonym
Abdominal aortic aneurysm, enlarged artery of the abdominal aorta

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: stiching st Elizabeth,Stichting St Elizabeth

Intervention

Keyword: Abdominal aortic aneurysm, endovascular aneurysm repair Nellix endoprosthesis, FDG-PET imaging

Outcome measures

Primary outcome

FDG, Standard Uptake Values (SUV).

Secondary outcome

inflammation assessed by known inflammatory markers (e.g. CRP and leukocyte

count).

Study description

Background summary

Abdominal aortic aneurysm (AAA) is a prevalent disorder affecting 4.3 to 8.8% of men over the age of 60.1 Since the introduction of endovascular aneurysm repair (EVAR) in the early 1990*s, EVAR is performed in the majority of patients to prevent rupture.
One of the most devastating complications following EVAR is infection of the used endograft. Because of the high mortality associated with endograft infection, patients with a possible graft infection are treated with life-long broadspectrum antibiotics. Unfortunately, the diagnosis is difficult and PET imaging is often used as a tool to support diagnosis and to initiate life long antibiotic treatment or even secondary surgery.
Following endograft placement, the aortic wall shows extensive inflammation and increased metabolic activity. This is probably related to the insertion of the prosthetic graft material itself and the mechanical manipulation and deformation (strain) following endograft placement. The increased metabolic activity in the aortic wall following EVAR might result in positive PET findings. This could limit the use of PET imaging to identify endograft infection and questions the use of life-long broadspectrum antibiotic treatment in patients with a PET positive finding following EVAR.
The Nellix endoprosthesis is a relatively new device used for EVAR. The difference with traditional endografts is that the entire aneurysm is filled by two polymer-filled endobags, with two balloon expandable stents preserving flow

to the lower extremity. With this new device endoleaks, aneurismal flow outside the stents, are less likely to occur and also migration is rare. In present literature there is no data on the degree of physiologic inflammation following implantation of a Nellix device and the value of postoperative FDG-PET imaging to detect infection is not known. This makes the diagnosis of infection following Nellix implantation extremely difficult.

Study objective

To determine FDG uptake following uncomplicated EVAR using the Nellix endoprosthesis. Does uncomplicated EVAR using the Nellix endoprosthesis result in increased FDG uptake and false positive PET imaging? .

Study design

Observational case series (pilot).

Study burden and risks

Regular preoperative and follow-up imaging for EVAR planning and follow-up using the Nellix endoprosthesis consists of Computed Tomography Angiography preoperative and at six weeks, six months and one year after EVAR. In this study the preoperative and first follow-up CTA (6 weeks after EVAR) will be replaced by a PET/CTA. Regular blood samples are collected prior to CTA to determine kidney function. For patients included in the study, additionally several inflammation markers will be determined. (leukocyte count and CRP).

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

•scheduled endovascular aneurysm repair using the Nellix endoprosthesis.
•Informed consent

Exclusion criteria

Diabetes Mellitus type 1 en 2.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2015
Enrollment:	10

Type:	Actual

Ethics review

Approved WMO Date:	02-10-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-12-2014
Application type:	Amendment
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	NL50251.091.14

Study results

Date completed:	27-06-2018
Actual enrolment:	10