

# The effect and usefulness of yearly standardised imaging surveillance in patients that underwent endovascular repair of an asymptomatic abdominal aortic aneurysm.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON28430

### Source

NTR

### Brief title

ODYSSEUS

### Health condition

Abdominal aortic aneurysm, imaging surveillance, endovascular aortic repair

Abdominaal aorta aneurysma, standaard beeldvorming, endovasculaire aorta ingreep

## Sponsors and support

**Primary sponsor:** Academic Medical Center, Amsterdam, the Netherlands

**Source(s) of monetary or material Support:** ZonMw, the Hague, The Netherlands

## Intervention

## Outcome measures

### Primary outcome

the main outcome parameters are reinterventions and survival stratified for patients with and without yearly imaging surveillance during 6-11 years follow-up (in patient with a normal initial postoperative CTA)

### Secondary outcome

- To assess type I, type II, type III and type IV endoleak, graft or outflow (iliac) occlusion, aneurysm rupture, endograft infection stratified for patients with complete and incomplete yearly standardised imaging surveillance (and a normal initial postoperative CTA).
- To assess reintervention free survival stratified for patients with complete and incomplete yearly standardised imaging surveillance (and a normal initial postoperative CTA).
- To assess if there is a difference in the number of patients with aneurysm rupture stratified for patients with complete and incomplete yearly standardised imaging surveillance (and a normal initial postoperative CTA).
- To assess if there is a difference in the number of reinterventions or mortality between follow-up imaging with CTA or DUS.
- To assess if there is a difference in costs stratified for patients with complete and incomplete yearly standardised imaging surveillance (and a normal initial postoperative CTA).

## Study description

### Background summary

Rationale: Yearly standardised imaging surveillance is recommended to all patients after endovascular aortic repair (EVAR) to detect complications requiring reintervention. However, this also causes a burden on both patients and the healthcare system.

Objective: The objective of this study is to evaluate whether imaging surveillance frequency can be safely reduced in a select group of EVAR patients, i.e. patients with an asymptomatic infrarenal abdominal aortic aneurysm (AAA) that underwent EVAR without abnormalities on the initial postoperative CTA.

Study design: Our study design is a multicentre retrospective cohort study in 16 medical centres.

Study population: All adult patients, with an asymptomatic infrarenal AAA that underwent

elective EVAR between January 2007 and January 2012.

Main study parameters: The number of patients with reinterventions and survival stratified for patients with and without yearly standardised imaging surveillance in patient without abnormalities on their initial postoperative CTA.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients from whose medical record we collect data will not benefit or be harmed by our study. However, we hope that the extracted information from these medical records, supports our theory about possible reducing the imaging surveillance frequency within ten years after EVAR in patients with an asymptomatic infrarenal AAA who underwent EVAR without abnormalities on initial postoperative CTA. Hence, future patients will benefit from this knowledge.

### **Study objective**

Can imaging surveillance frequency be safely reduced in a select group of EVAR patients, i.e. patients with an asymptomatic infrarenal abdominal aortic aneurysm (AAA) that underwent EVAR without abnormalities on the initial postoperative CTA.

### **Study design**

All adult patients, with an asymptomatic infrarenal AAA that underwent elective EVAR between January 2007 and January 2012.

### **Intervention**

standardised imaging surveillance

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

- Age above 17 years
- Patients that underwent EVAR between 2007 and 2012
- Patient with an initial postoperative CTA within 60 days after EVAR
- Patients with an asymptomatic infrarenal abdominal aortic aneurysm

### Exclusion criteria

- Connective tissue disease
- Patients that objected to their retrospective data being used

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	1997
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	05-04-2018
Application type:	First submission

## 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	NL6953
NTR-old	NTR7141
Other	843004119 ZonMw : W18_102 #18.130 MEC AMC /

## Study results