The pro and cons of yearly imaging after minimally invasive aorta repair according to patients

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20409

Source
NTR

Brief title
ODYSSEUS prospective

Health condition

Abdominal Aortic Aneurysm, Endovascular aortic repair, Standardised imaging surveillance, Test Anxiety Scale, Surveys and Questionnaires

Sponsors and support

Primary sponsor: Amsterdam UMC, location Academich Medical Center (AMC)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

To detect differences in anxiety levels directly after imaging surveillance and before obtaining the imaging result compared to baseline anxiety levels.

Secondary outcome

- differences in global and physical health directly after imaging surveillance and before obtaining the imaging result compared to baseline anxiety levels.

- the necessity of standardised surveillance according to patients

Study description

Background summary

Rationale: Evidence suggests that standardised imaging surveillance may not be beneficial to all patients after endovascular aortic repair (EVAR). Therefore, when weighing the benefits and harms of yearly standardised imaging surveillance after endovascular aortic repair (EVAR), it is important to include the patients' perspective.

Objective: Defining the negative or positive impact of standardised imaging surveillance in EVAR-patients.

Study design: a multicentre prospective cohort study in 4 medical centres.

Study population: All adult patients, with an infrarenal asymptomatic abdominal aneurysm (AAA) visiting the outpatient clinic of a participating vascular surgery department or vascular medical centre for EVAR follow-up.

Intervention (if applicable): Our study does not entail a (new) medicinal or surgical intervention. Patients will be asked to fill out standardized questionnaires after follow-up imaging and in between two follow-up visits.

Main study parameters/endpoints: The level of anxiety at different times during follow-up.

Study objective

We hypothesize that anxiety symptoms worsen after follow-up imaging compared to patients baseline anxiety levels.

Study design

All adult patients, with an infrarenal asymptomatic abdominal aneurysm (AAA) visiting the outpatient clinic of a participating vascular surgery department for EVAR follow-up

Intervention

Our study does not entail a (new) medicinal or surgical intervention. Patients will be asked to fill out standardised questionnaires.

Contacts

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Eligibility criteria

Inclusion criteria

- Age above 17 year

- Patients with an asymptomatic infrarenal abdominal aortic aneurysm

- Patient with imaging after EVAR

Exclusion criteria

- Insufficient understanding of the Dutch language or cognitively unable to complete Dutch questionnaires

- Life expectancy less than 1 year

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	138
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	31-07-2018
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	NL7214
NTR-old	NTR7413
Other	843004119 ZonMw : W18_226 #18.270 MEC AMC

Study results