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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28430

Bron
NTR

Verkorte titel
ODYSSEUS

Aandoening

Abdominal aortic aneurysm, imaging surveillance, endovacular aortic repair

Abdominaal aorta aneurysma, standaard beeldvorming, endovasculaire aorta ingreep

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam, the Netherlands
Overige ondersteuning: ZonMw, the Hague, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

standardised imaging surveillance

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Connective tissue disease

- Patients that objected to their retrospective data being used

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	1997
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6953
NTR-old	NTR7141
Ander register	843004119 ZonMw : W18_102 #18.130 MEC AMC /

Resultaten