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

Gepubliceerd: 31-07-2018 Laatst bijgewerkt: 13-12-2022

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

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

## Samenvatting

### ID

NL-OMON20409

**Bron**
Nationaal Trial Register

**Verkorte titel**
ODYSSEUS prospective

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Amsterdam UMC, location Academich Medical Center (AMC)
**Overige ondersteuning:** ZonMw

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age above 17 year

- Patients with an asymptomatic infrarenal abdominal aortic aneurysm

- Patient with imaging after EVAR

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

- Life expectancy less than 1 year

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Factorieel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-09-2018 |
| Aantal proefpersonen: | 138 |
| 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: | 31-07-2018 |
| 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 | NL7214 |
| NTR-old | NTR7413 |
| Ander register | 843004119 ZonMw : W18_226 #18.270 MEC AMC |

# Resultaten