

# Decision aid Evaluation by a Clinical trial in Abdominal aortic aneurysms: Improving Decision making.

Gepubliceerd: 05-11-2008 Laatst bijgewerkt: 18-08-2022

Providing AAA patients with a decision aid concerning watchful waiting or elective surgery will decrease their decisional conflict, increase their knowledge on treatment options, increase satisfaction and increase quality of life.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON28240

### Bron

NTR

### Verkorte titel

DECAID

### Aandoening

Abdominal Aortic Aneurysm (AAA)

Aneurysma Aortae Abdominalis

Medical Decision Making

Medische besluitvorming

Decision Aid

### Ondersteuning

**Primaire sponsor:** Academic Medical Center, Amsterdam

Department of Quality Assurance & Process Innovation

Department of Surgery

Department of Medical Psychology

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

- Decisional Conflict

## Toelichting onderzoek

### Achtergrond van het onderzoek

Background of the study:

Prevalence of the Abdominal Aortic Aneurysm (AAA) is 6% among the elderly male population. AAA is an asymptomatic disease, but implies a risk of rupture of the aneurysm. Whenever this occurs, the majority of patients will die due to severe internal bleeding within 24 hours. An elective operation can prevent rupture of the aneurysm, but may also induce mortality or severe morbidity due to the very procedure.

For surgeons, the choice between the risk of rupture during watchful waiting, or the risk of complications due to surgery is usually not clear-cut, mostly due to comorbid conditions with the patient. Therefore, patient preferences are of paramount importance.

A decision aid regarding treatment options for AAA could help patients and surgeons to make an informed choice. Decision aids translate scientific evidence regarding (the pro's and con's of) the treatment options into comprehensible patient information.

Moreover, patient preferences are elicited in the decision aid. Previous research has shown that patients' decisional conflict decreases, comprehension of treatment options increases, patients have more realistic expectations and they are more actively participating in decision making.

Objective of the study:

In this study, the effect of a decision aid regarding the choice between watchful waiting or surgical treatment of AAA is explored, regarding decisional conflict, knowledge, satisfaction, quality of life, anxiety and clinical endpoints.

Study design:

Randomised clinical trial, in which 170 subjects are randomised between (1) standard care and (2) standard care + decision aid

Study population:

Eligible trial participants are patients newly diagnosed with an infrarenal AAA presenting for the first time at one of the outpatient clinics of the participating hospitals to discuss their treatment options. Inclusion criteria are: patients diagnosed with an AAA based on ultrasonography (and CT-scanning in the case of an aneurysm of 5.5 cm and more), age >18 years and compos mentis. Exclusion criteria are: life expectancy of <6 months, insufficient knowledge of the Dutch language.

Intervention (if applicable):

Decision aid, comprising an interactive computer programme.

Primary study parameters/outcome of the study:

Decisional conflict

Secondary study parameters/outcome of the study (if applicable):

- Knowledge
- Satisfaction
- Quality of life
- Anxiety

Clinical endpoints (mortality, severe 30-day morbidity due to operation, rupture during watchful waiting)

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness (if applicable):

Because trial participation does not influence medical treatment, subjects will suffer no (physical) risks. Subjects are requested to spend time to complete 5 questionnaires (with in total 70 items) at 4 points in time, from the first visit to the outpatient clinic to 9 months after their treatment decision. Subjects in the intervention arm might be frightened by the additional information provided to them in the decision aid.

### **Doel van het onderzoek**

Providing AAA patients with a decision aid concerning watchful waiting or elective surgery will decrease their decisional conflict, increase their knowledge on treatment options, increase satisfaction and increase quality of life.

### **Onderzoeksopzet**

T0: inclusion and randomisation of the patient, first set of questionnaires

T1: patients in the intervention group study the decision aid

T2: second set of questionnaires after the treatment choice is made

T3: third set of questionnaires 3 months after T2

T4: fourth set of questionnaires 6 months after T3

### **Onderzoeksproduct en/of interventie**

A decision aid concerning the choice between watchful waiting and elective surgery of an AAA.

(The decision aid consists of information on AAA, medical evidence on benefits and risks of both treatment options, and it elicits patients' preferences)

## **Contactpersonen**

### **Publiek**

Academic Medical Center (AMC)

A. Goossens  
Amsterdam  
The Netherlands

a.goossens@amc.nl

## Wetenschappelijk

Academic Medical Center (AMC)

A. Goossens  
Amsterdam  
The Netherlands  
a.goossens@amc.nl

## Deelname eisen

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

1. Patients newly diagnosed with an AAA based on ultrasonography (and CT-scanning in the case of an aneurysm of 5.5 cm and more).
2. Age >18 years.
3. Compos mentis.

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

1. Life expectancy of <1 year.
2. Insufficient knowledge of the Dutch language.

## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd

Controle: N.v.t. / onbekend

## Deelname

Nederland  
Status: Werving gestopt  
(Verwachte) startdatum: 03-11-2008  
Aantal proefpersonen: 170  
Type: Werkelijke startdatum

## Ethische beoordeling

Positief advies  
Datum: 05-11-2008  
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	NL679
NTR-old	NTR1524
Ander register	MEC AMC : 08/218
ISRCTN	ISRCTN wordt niet meer aangevraagd

# Resultaten

## Samenvatting resultaten

N/A