

A randomised trial on communicating evidence with a decision aid in abdominal aortic aneurysm surgery: improving informed decision making in patients and surgeons

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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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32818

Source

ToetsingOnline

Brief title

DECAID

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym

Aneurysm of the abdominal artery

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Abdominal Aortic Aneurysm, Decision Aid, Informed decision making

Outcome measures

Primary outcome

Decisional conflict

Secondary outcome

Knowledge

Satisfaction

Quality of life

Anxiety

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

Study description

Background summary

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.

Study objective

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

Intervention

Decision aid, comprising an interactive computer programme.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Patients 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

Exclusion criteria

1. life expectancy of <6 months
2. insufficient knowledge of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2008
Enrollment:	170
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL24145.018.08