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

No registrations found.

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

Summary

ID

NL-OMON28240

Source
NTR

Brief title
DECAID

Health condition

Abdominal Aortic Aneurysm (AAA)
Aneurysma Aortae Abdominalis
Medical Decision Making
Medische besluitvorming
Decision Aid

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Department of Quality Assurance & Process Innovation
Department of Surgery
Department of Medical Psychology

Intervention

Outcome measures

Primary outcome

- Decisional Conflict

Secondary outcome

- Knowledge

- Satisfaction

- Quality of Life

Study description

Background summary

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 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

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

- Knowledge

- Satisfaction

- Quality of life

- Anxiety

Clinical enpoints (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.

Study objective

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.

Study design

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

Intervention

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)

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Life expectancy of <1 year.

2. Insufficient knowledge of the Dutch language.

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2008
Enrollment:	170
Type:	Actual

Ethics review

Positive opinion

Date:	05-11-2008
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	NL679
NTR-old	NTR1524
Other	MEC AMC : 08/218
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A