

Quality of life, anxiety and personality in patients with an abdominal aortic aneurysm

Published: 13-11-2007

Last updated: 10-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

Summary

ID

NL-OMON31877

Source

ToetsingOnline

Brief title

Psychological factors in AAA patients

Condition

- Aneurysms and artery dissections

Synonym

localized bulge of the abdominal aorta; localized blood-filled dilation of the abdominal aortic wall

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

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

Intervention

Keyword: Aneurysm, Anxiety, Depression, Quality of life

Outcome measures

Primary outcome

Quality of life

Aneurysm growth (diameter difference over 1.5 years)

Surgical events

Secondary outcome

N/A

Study description

Background summary

The knowledge of having a small aortic abdominal aneurysm (AAA) for which a wait-and-see policy is customary may bring about anxiety and decreased quality of life. To date, no prior study has focused on the psychological effects of the wait-and-see policy in AAA. Therefore the present study will prospectively examine the levels of anxiety, depression and quality of life in patients with a small AAA and will assess these as predictors of aneurysm growth, incidence of surgical repair and death.

Study objective

The objective of the current study is to determine whether the wait-and-see policy affects anxiety levels and quality of life in patients with aortic abdominal aneurysms between 3 and 5.5 cm in diameter. Furthermore, we aim to examine the influence of anxiety and personality type on aneurysm growth and incidence of surgical repair or death in patients with a small abdominal aortic aneurysm. A third objective is to examine whether quality of life improves in patients with an aortic abdominal aneurysm of 5.5 cm or greater after open or endovascular repair.

Study design

Prospective, observational study

Study burden and risks

Burden of risk is considered minimal, since only questionnaires are asked to be filled out.

Contacts

Public

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NL

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Diagnosis of a small abdominal aortic aneurysm with a diameter of between 3.0 and 5.5 cm

Exclusion criteria

- Acute aneurysm of the abdominal aorta
- Age over 75
- Significant cognitive impairment (e.g. dementia)
- Insufficient command of the Dutch language

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2007

Enrollment: 150

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Brabant (Tilburg)

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

CCMO

ID

NL20131.028.07