Screening Cardiovascular patients for Aortic aNeurysms

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

Summary

ID

NL-OMON37883

Source
ToetsingOnline

Brief title
SCAN

Condition

- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Medtronic,Medtronic B.V.

Intervention

Keyword: Aneurysm, Aorta, Screening

Outcome measures

Primary outcome

AAA prevalence in patients with PAD and patients with carotid stenosis.

Secondary outcome

- Quality of life as measured by Medical Outcomes Study, Short Form 36 (SF-36)

- Illness Perception measured 'Illness Perceptions Questionnaire, short

version (IPQ-K)

- Division AAA diameter under age categories

- Percentage of patients who choose to have a screening ultrasound

- Usability and reliability of Vscan* (GE Healthcare)

Study description

Background summary

An aneurysm of the abdominal aorta (AAA) is a local dilatation of the aorta in the abdomen (diameter >= 3 cm). The aneurysm generally causes no symptoms and is often discovered by accident. The risk of an aneurysm is that it can tear. In case that happens the risk of death is 80%. In 2000, the number of people with AAA in the Netherlands is estimated at 86,100 (69,400 men and 16,700 women) and this incidence will only increase. In the same year 830 persons (620 men and 210 women) deceased due to an AAA.
The high mortality in patients with ruptured aneurysm in comparison with the low mortality due to a preventive operation of a non-ruptured aneurysm has led to research of the (cost)effectiveness of population-based screening studies for AAA. A Cochrane review showed that screening people for AAA leads to a significant reduction in AAA-related mortality in men aged 65 to 79. It also has been shown that screening of men in the Netherlands is costeffective. There is still insufficient evidence to show an effect on the total mortality in women. A nationwide screening program for AAA in the Netherlands has not yet started.

Screening of groups with an increased prevalence may be more effective. It is known that the prevalence is higher among patients with PAD and patients with carotid stenosis compared to the prevalence from population-based screening studies. Both groups of patients have an increased risk of other cardiovascular diseases, making that the life expectancy after a preventive surgery may not be increased. Both open and endovascular surgery have risks and complications so that the life expectancy can also be shortened.
Moreover, the diagnosis after screening for AAA is likely to affect the psyche of the patient and his/her partner. A Cochrane review shows there are no data available about the quality of life after assigning the diagnosis of AAA in screening studies. The available literature describes only the post-screening difference in quality of life after negative versus positive screening. So far, baseline measurements were not included in the analysis.

Study objective

The research focuses on the active screening of high prevalence patients and the diagnosis of AAA. This study aims to establish an effective screening protocol and determining a higher prevalence in patients with PAD and patients with carotid stenosis that visit the outpatient clinic of the Catharina Hospital. At the same time, there is the opportunity to inform the patient in detail about the increased risk of having an AAA and to determine the influence of the AAA diagnosis on the quality of life.

Study design

Patients with PAD and patients with carotid stenosis who meet all inclusion criteria and none of the exclusion criteria will be asked to participate in this research by using shared-decision making. They are given at least 3 days for reflection, before deciding to participate in the study and sign informed consent. Patients who give consent will be asked to fill in the SF-36 questionnaire. Then the patient will receive an ultrasound of the aorta by using a Vscan * , performed by a nurse practitioner of the vascular surgery department, to determine the initial diameter. The following possibilities exist:
- The diameter is <3 cm: the patient is informed that he/she has no aneurysm.
- The diameter >= 3 cm: the patient is referred for an ultrasound examination of the aorta at the Vascular Laboratory.
- In case the diameter is confirmed, the patient will follow the standard procedure that has been followed in the Catharina Hospital for decades in case of AAA coincidence detection;
- Patients with a diameter <5 cm are periodically (every 3, 6 or 12 months) checked according to hospital protocol.
- Patients with a diameter >= 5 cm suitable for surgery (according to international guidelines), get a CT scan followed by an open or endovascular surgery for the aneurysm according to usual care.

Three months after the results of the ultrasound, the patient is asked to fill in the SF-36 questionnaire and the IPQ-K questionnaire.
Besides this, we gather the medical information of new patients, who already know if they have an aneurysm or not.

Study burden and risks

Patients will be asked 2 times to fill in a questionnaire. Patients are given a non-invasive ultrasound of the abdominal aorta. This is least stressful for the patient and brings no direct risks with them. In case that an aneurysm of the abdominal aorta is detected, the patient may experience this as a mental burden. In case it comes to an operation, the patient runs the risks associated with the operation. By informing the patient in detail about the burdens and risks by using shared-decision making, the patient may take a well considered decision about participation in this study.

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

- Patients with peripheral arterial disease (ankle brachial pressure index < 0.90 and/or a decline of > 0.15 after exercise test) and/or carotis stenosis (>= 50%)
- Men and women
- Age > 55 years

Exclusion criteria

- Patients unfit for endovascular or open surgery (as judged by vascular surgeon)
- Failure to master the dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2012
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2012
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL39959.060.12