Optimal early recognition of persons at high risk of aneurysmal subarachnoid haemorrhage

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Objective 1)To determine the cost-effectiveness of screening for and preventive treatment of UIAs in persons with FDRs with UIAs. We will therefore assess the prevalence of UIA in persons with >=1 FDR with an UIA, the costs of the screening, the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON55759

Source
ToetsingOnline

Brief title
ERASE

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
Intracranial aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: aneurysm, hemorrhage, intracranial, subarachnoid

Outcome measures

Primary outcome

Objective 1)

- the prevalence of UIA in persons with >=1 FDR with an UIA

Objective 2)

- the prevalence of potential risk factors for UIA development in persons with

>=1 FDR with an UIA

Objective 3)

- the prevalence of UIA in persons with >=1 FDR with an UIA

Secondary outcome

Objective 1)

- costs of screening for and preventive treatment of UIA

- clinical outcome after preventive treatment of an UIA identified with

screening

- decision model studying cost-effectiveness expressed in costs per QALY

Objective 2)

- prediction model of risk of UIA in persons with >=1 FDR with an UIA

Objective 3)

- correlation of imaging markers on 3T and 7T MRA and biopsy findings of the

UIA wall

Study description

Background summary

Rupture of an intracranial aneurysm (IA) results in an aneurysmal subarachnoid hemorrhage (aSAH), a subset of stroke occurring at relatively young age and more often in women. It carries a high case morbidity and fatality, and has a high socioeconomic burden. Lifetime risk of aSAH in the general population is highest for persons with a positive family history for aSAH. Screening with Magnetic Resonance Angiography (MRA) can detect unruptured IAs (UIAs), which can then be treated to prevent future aSAH. Currently, only for first degree relatives (FDRs) of aSAH patients there is evidence that screening is effective. For FDRs of patients with UIAs (which occur in 3% of the population) studies on effectiveness of screening have not been performed. Also, the efficiency of the current screening strategy could be improved by identifying high-risk individuals better. This identification could be improved by new additional imaging markers for UIA development. Our aim is 1. to determine the benefits and risks of screening for UIAs within persons with FDRs with UIA; 2. to determine if persons with FDRs with UIA can be divided in groups with a different risk for UIA development and 3. to assess potential imaging markers for UIA development.

Study objective

Objective 1)
To determine the cost-effectiveness of screening for and preventive treatment of UIAs in persons with FDRs with UIAs.
We will therefore assess the prevalence of UIA in persons with >=1 FDR with an UIA, the costs of the screening, the effects of screening in terms of numbers of life years in good quality of life gained by preventing aSAH and the number of quality adjusted life years (QALYs) lost through side effects of screening

Objective 2)
To determine if persons with FDRs with UIA can be divided in groups with a different risk for UIA development based on risk factors. We will therefore assess the prevalence of potential risk factors for UIA development in persons with >=1 FDR with an UIA.

Objective 3)

To assess potential imaging markers for UIA development on 3T and 7T MRA.

Study design

A monocenter observational prospective screening cohort study in first degree family members of a consecutive series of index patients with UIA. Costs and effects will be determined by means of a modeling approach.

Study burden and risks

The burden associated with participation consists of one MRA, six times an E-questionnaire about quality of life, 1-2 times blood pressure measurement (depending on result of screening MRA), 0-1 times physical examination (depending on the result of the screening MRA) and an additional MRA in case of positive screen (optional). Participants will be invited to visit the outpatient clinic 1-5 times during this study (depending on the result of the screening MRA).
We believe that the risks associated with participation are small, since the procedures used are common in daily clinical practice. This outweighs the relevance of this study for future screening in this patientcohort.

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

- Age between 20 and 70 years
- At least one first degree relative with an unruptured intracranial aneurysm identified by MRA, CTA or conventional angiography

Exclusion criteria

- People who do not speak Dutch well enough to give informed consent
- Any first degree relative with an aneurysmal subarachnoid hemorrhage
- A history of an aneurysmal subarachnoid hemorrhage and/or unruptured intracranial aneurysm
- A history of polycystic kidney disease, Ehlers-Danlos, or fibromuscular dysplasia
- Relative contraindication(s) for MRA, e.g. pregnancy, an internal metal device such as a pacemaker, or claustrophobia
- A serious condition that would interfere with the treatment of an UIA, e.g. severe comorbidity or reduced life expectancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2017

Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL59910.041.16