@neurIST
Integrated biomedical informatics for the management
of intracranial aneurysms

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To establish an operational reference database on intracranial aneurysms encompassing clinical and genetic data on at least 800 patients, 400 controls and 400 relatives of patients where a familial trait is recognized, together with imaging data on...

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

Summary

ID

NL-OMON30929

Source
ToetsingOnline

Brief title
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Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
arterial bulging, arterial widening

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: EU

Intervention

Keyword: epidemiology, genetics, imaging, intracranial aneurysm

Outcome measures

Primary outcome

a point estimation of relative risk for patients with certain genetic

variations (which have to be established)

Secondary outcome

To perform genome-wide association studies to search for other susceptibility

loci.

To obtain reference geometries and perform computational fluid dynamics

analyses for at least 100 patients

Study description

Background summary

Unruptured intracranial aneurysms occur in 1 to 6% of the population. Amongst those with IA, the incidence of rupture is relatively low, of the order of 10 / 10,000 per year. The consequences of rupture however are severe: 45% of individuals patients with a ruptured aneurysm will die within a month of the event.
Because roughly 10% of patients with aneurismal SAH have first or second degree relatives with SAH or unruptured IA aneurysms there is a likely genetic component to IA.

Study objective

To establish an operational reference database on intracranial aneurysms encompassing clinical and genetic data on at least 800 patients, 400 controls and 400 relatives of patients where a familial trait is recognized, together with imaging data on at least 600 patients.

To identify genetic variations associated with increased risk (relative risk >1.5, allele frequency 0.35 - 0.65) for intracranial aneurysm with or without SAH on the basis of patient groups of at least 400 cases.

Study design

case-control study

Study burden and risks

burden:
venapunction for 30 ml whole blood
CTA - dose of radiation
filling out questionnaire

benefit:
for this patient: nil
for future patients: increased knowledge

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

unruptured intracranial aneurysm

Exclusion criteria

inability to participate, due to severe mental or physical disabilities.
(severe) claustrophobie (to anxious to undergo a CT-scan)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	13-12-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-10-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16981.078.07