Subarachnoid Bleeding Prognosis by Acutely RupTured Aneurysm Study

Published: 22-02-2019
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Objective: The aim of this comparative study is to identify the highest value-based practice for ruptured intracranial aneurysm patients in the short-, medium-, and long term by prospective registration.

Ethical review	Not approved
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON48437

Source
ToetsingOnline

Brief title
SPARTA

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
aneurysma, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Sint Jacobus Stichting

Intervention

Keyword: aneurysm, stroke, subarachnoid hemorrhage

Outcome measures

Primary outcome

Main study parameters/endpoints: Disease specific patient reported outcome, functional outcome and surgical outcome 1, 2, 5 and 10 years after treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will receive normal care during their hospital stay. For study purposes, health questionnaires and functional outcome will be assessed at baseline and before discharge. During follow-up, patients will be asked to complete several questionnaires and tests and they will receive follow-up imaging to assess treatment success. These tests, questionnaires and imaging will take approximately 2 hours to complete. In order to improve comparability between centers, we will use a uniform protocol during follow-up. Some patients will be followed more regularly in this protocol as compared to their local guidelines. However, we think this does not attribute to significant risk for our study subjects. Extended follow-up could even address potential health problems that would have gone unnoticed previously. We argue that the additional risk of additional imaging with contrast (preferably and most often done by MRI) does not attribute to a significant health risk for patients.

Measurements will be done in the hospital, the rehabilitation center, or in the patient*s home. Patients could become tired after a measurement moment or follow-up visit, but this tiredness will not last. Also, patients may

be confronted with their morbidity by functional tests. The data acquired in this study will be used to identify the optimal and most cost-effective treatment strategy for intracranial aneurysm patients. This will benefit future intracranial aneurysm patients.

Secondary outcome

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Study description

Background summary

Rationale: Ruptured brain aneurysms can be treated by open surgical treatment or endovascular treatment. Which treatment has the highest value-based practice remains unclear since most previous research is biased by selection. We therefore will perform a comparative effectiveness study.

Study objective

Objective: The aim of this comparative study is to identify the highest value-based practice for ruptured intracranial aneurysm patients in the short-, medium-, and long term by prospective registration.

Study design

Study design: This study will have a multi-center prospective cohort design with clinical data-registration. Patients will be included when they present with a ruptured intracranial aneurysm and will have a follow-up of 10 years.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will receive normal care during their hospital stay. For study purposes, health questionnaires and functional outcome will be assessed at baseline and before discharge. During follow-up, patients will be asked to complete several questionnaires and tests and they will receive follow-up imaging to assess treatment success. These tests, questionnaires and imaging will take approximately 2 hours to complete. In order to improve comparability between centers, we will use a uniform protocol

during follow-up. Some patients will be followed more regularly in this protocol as compared to their local guidelines. However, we think this does not attribute to significant risk for our study subjects. Extended follow-up could even address potential health problems that would have gone unnoticed previously. We argue that the additional risk of additional imaging with contrast (preferably and most often done by MRI) does not attribute to a significant health risk for patients.
Measurements will be done in the hospital, the rehabilitation center, or in the patient*s home. Patients could become tired after a measurement moment or follow-up visit, but this tiredness will not last. Also, patients may be confronted with their morbidity by functional tests. The data acquired in this study will be used to identify the optimal and most cost-effective treatment strategy for intracranial aneurysm patients. This will benefit future intracranial aneurysm patients.

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 a diagnosis of a ruptured intracranial aneurysm on arterial angiogram or CTA.
- Patients with an age over 18 years at presentation.

Exclusion criteria

- Patients with inadequate command of the languages used in the questionnaires (English, Dutch or German).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1500
Type:	Anticipated

Ethics review

Not approved

Date:	22-02-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL68178.098.19