Study on Prognosis of Acutely Ruptured intracranial Aneurysms

Published: 16-06-2020
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The goal of this study is to investigate which treatment(-s) lead to the best outcome by using existing variation of practice.

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

Summary

ID

NL-OMON55176

Source
ToetsingOnline

Brief title
SPARTA

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
brain aneurysm, 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, functional outcome, practice variation, subarachnoid haemorrhage

Outcome measures

Primary outcome

The primary outcome is a standardised functional measurement, the score on modified Rankin scale after one year..

Secondary outcome

Standardised functional outcome measurements:

- modified Rankin scale after six months, two years, five years and ten years

- extended Glasgow Outcome Scale after six months, one year, two years, five years and ten years

Standardised cognitive status and mood/fatigue measurement:

- Montreal Cognitive Assessment after six months, one year, two years, five years and ten years

- Rancho los Amigos Levels of Cognitive Functioning Scale after six months, one year, two years, five years and ten years

- Short form of the multidimensional Fatigue Syptom Inventory after six months, one year, two years, five years and ten years

- Hospital Anxiety and Depression Scale after six months, one year, two years, five years and ten years

Standardised measurement of quality of life and reporting of cost-effectivity:

- EQ-5D and visual analogue scale after six months, one year, two years, five

years and ten years

- 36-question short form questionnaire after six months, one year, two years, five years and ten years

- Quality Adjusted Life years and cost-utility analysis with patient reported costs through patient diaries

Relation of complications of subarachnoid haemorrhages and their treatment with the outcomes above:

- hydrocephalus and drainage of cerebrospinal fluid

- delayed cerebral ischemia and its treatment

- rebleeding and its treatment

- recanalisation and its treatment

Role of:

- mobilisation and early rehabilitation in the hospital with the outcomes above

- regional organisation of care, amongst others the referral area, with the outcomes above

Prediction of outcomes above and occurrence of complications with clinical and radiological data from presenation

Study description

Background summary

Most subarachnoid haemorrhages are caused by a rupture of an intracranial aneurysm. They have a significant impact on the quality of life of patients and even their survival. The aneurysm itself can be treated through an open microsurgical procedure or through an endovascular procedure. Variation still exists in the treatment, despite previous studies. Knowledge about long term outcome is scarce, especially about functional and cognitive outcome. Not much is known about cost-effectivity of the different treatment modalities, especially on long-term follow-up.

Study objective

The goal of this study is to investigate which treatment(-s) lead to the best outcome by using existing variation of practice.

Study design

An observational prospective cohort study in multiple hospitals in the Netherlands will be performed. Patients will be included on presentation with a subarachnoid haemorrhage and will receive regular therapy as indicated by local guidelines. There will be no outside influence on this treatment.

Study burden and risks

Patients will receive normal care during their hospital stay and after. There will be no invasive measurements or experimental treatments for this study.

Patients will be asked to complete questionnaires during their hospital stay and afterwards during follow-up consultations. They will be asked to answer questions. Some additional questions will be asked during the follow-up consultation to complete standardised measurememnt and a physical examination will take place. The completion of the questionnaires can cause temporary fatigue and takes time. If patients have difficulty completing the questionnaires themselves, their representative can help.

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

- Confirmed diagnosis of subarachnoid haemorrhage on CT-scan or lumbar puncture (in the presence of a negative CT-scan)
- Age eighteen years or over at presentation.

Exclusion criteria

- Subarachnoid haemorrhage deemed most likely of *perimesencephalic* origin after consideration of history, clinical examination and radiological findings (including angiographic imaging)
- Subarachnoid haemorrhage deemed most likely of post-traumatic origin after consideration of history, clinical examination and radiological findings (including angiographic imaging)
- Diagnosis of intracerebral arteriovenous malformations or dural arteriovenous fistula.
- No diagnosis of intracranial aneurysm at six months after onset of symptoms.
- Not mastering 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):	14-07-2021
Enrollment:	880
Type:	Actual

Ethics review

Approved WMO

Date:	16-06-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	12-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	27-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	22-01-2024

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-02-2025
Application type:	Amendment
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	NL71261.058.19