ISRCTN16523175 https://doi.org/10.1186/ISRCTN16523175

The usefulness of measuring oxygen and metabolites in the brain after aneurysm rupture in preventing secondary stroke

Submission date
25/07/2019

Recruitment status
No longer recruiting

Registration date
21/08/2019

Overall study status
Completed

Last Edited
08/09/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The current definition of delayed cerebral ischemia (DCI) is based on clinical characteristics and limited to awake patients. This largely precludes the use in poor-grade subarachnoid hemorrhage (SAH) patients, creating the need for additional parameters to evaluate the unconscious patient. Invasive neuromonitoring (INM) allows for continuous registration of brain metabolic functioning and may enable timely detection of metabolic crises in high-grade SAH patients. The aim of this trial is to analyze the effects introducing INM as a diagnostic tool on clinical decision-making, applied treatment and eventually, clinical outcome.

Who can participate?
All patients referred to a single tertiary care center between 2010 and 2018 with an aneurysmal subarachnoid hemorrhage.

What does the study involve?
The study has an observational design. It involves the comparison of two groups of similar patients, one in which INM was available and one in which it was not available as a diagnostic tool. Both cohorts are separated in time creating potential selection and information bias for which cannot be actively corrected. We will rigorously compare groups for any differences in baseline characteristics to exclude most relevant selection bias.

What are the possible benefits and risks of participating?
We anticipate that invasive neuromonitoring contributes to early identification of patients suffering delayed cerebral ischemia and selecting those who will profit from treatment faster. If this is the case, earlier treatment initiation in the appropriate selected patient can contribute to better outcome. Invasive monitoring carries however some potential procedural risks e.g. infection, hemorrhage and technical difficulties leading to false measurements.

Where is the study run from?
The study is run and performed and the neurointensive care unit of the department of neurosurgery at the university hospital in Aachen, Germany.

When is the study starting and how long is it expected to run for?
The trial has started in January 2014 and ended in December 2018.

Who is funding the study?
The trial is funded by the university hospital Aachen, Germany.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DCI-INM-r-Co

Study information

Scientific Title
The effectiveness of invasive neuromonitoring in high-grade subarachnoid hemorrhage patients - a prospective cohort study

Acronym

DCI-INM-r-Co

Study objectives
Invasive neuromonitoring in subarachnoid hemorrhage patients leads to earlier detection of delayed ischemic events. This results in an earlier treatment initiation and potentially in a better patients outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2014, the ethics committee of the university hospital of Aachen (Pauwelstrasse 30, 52064 Aachen, Germany; +49/241.80.89963; ekaachen@ukaachen.de).

Study design
The study has been designed as a part retrospective, part prospective cohort trial.

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Delayed cerebral ischemia occurring after subarachnoid hemorrhage.

Interventions
This being an observational trial, all patients are treated according to the hospitals/departments standard operating procedure. We are comparing two historical groups of which data has been collected prospectively. Starting in 2014, invasive monitoring for delayed cerebral ischemia became available in our neuro-intensive care unit. This means that eligible patients, with a poor-grade subarachnoid hemorrhage were considered for placement of monitoring probes. In this case, a small surgical procedure was performed in which two measurement probes were implanted in the left or right frontal lobe. This procedure is part of our standard of care. The goal of this observational analysis is to investigate whether this additional diagnostic procedure contributed to more adequate and effective treatment of delayed cerebral ischemia.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
N/A

Primary outcome measure
Clinical outcomes as measured using the extended Glasgow outcome scale after 12 months. Data is collected prospectively during regular follow-ups and missing information is either appended by analysis of patients files or a structured telephone interview by a blinded assessor.

Secondary outcome measures
1. GOS-E at discharge; GOS-E at 6 months measured and evaluated as mentioned above.
2. Overall mortality.
3. The lag between ictus and first treatment triggering DCI event (days), as is clear from patients files.
4. The absolute number of CT investigations performed during the DCI time frame, in every patient. This as an indirect measurement of reliance in clinical decision making, on the measurements made by the invasive monitoring.
5. The prevalence of silent infarctions (the occurrence of a demarcated infarction as the first sign of ongoing DCI). This is measured by investigation of patients CT and/or MRI images by a blinded observer.
6. The prevalence of overall DCI related infarction as is apparent in clinical files and medical imaging.
7. The prevalence of DCI related mortality, as is apparent in clinical files.

Overall study start date
17/04/2014

Completion date
01/11/2019

Eligibility

Key inclusion criteria
1. Suffered an aneurysmal subarachnoid hemorrhage.
2. Aged between 18 and 99 years old.
3. The hemorrhage has to present with a Hund & Hess grade of 3 or higher.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

200

Total final enrolment
190

Key exclusion criteria
1. The occurrence of early angiographical vasospasms in the first diagnostic angiography.
2. Subarachnoid hemorrhage not cause by aneurysm rupture.

Date of first enrolment
25/07/2018

Date of final enrolment
24/06/2019

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Aachen, Germany
Pauwelstrasse 30
52074 Aachen
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Sponsor information

Organisation
University Hospital Aachen

Sponsor details
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Sponsor type
University/education

Website
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ROR
https://ror.org/02gm5zw39

Funder(s)

Funder type
University/education

Funder Name
University Hospital Aachen

Funder Name
RWTH Aachen University

Alternative Name(s)
Rhine-Westphalia Institute of Technology Aachen, RWTH Aachen, Rheinisch-Westfälische Technische Hochschule Aachen

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Publication and dissemination plan
After statistical analysis, date should be ready for publication near the beginning of 2020.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
Date is stored on a centralized databank stored on the server of the medical faculty of the university of Aachen. There is no web link as the data can only be accessed via our institutional

intranet. Only members of the vascular research team of the department of neurosurgery, have access to these data. After completion of the data sheets, patient names and other identifiers are replaced by a single patient identification code.

Anonymized raw data can be made available on demand to researcher who are have appropriate qualifications. Whether to provide the data will remain an individual decision of our research team. The raw data consists out of spreadsheets in .xslx format. This data can be used for redo statistics or additional analyses.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/05/2020	08/09/2021	Yes	No