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Concomitant intraventricular fibrinolysis and low-frequency rotation after severe subarachnoid hemorrhage

Submission date
18/07/2012

Recruitment status
No longer recruiting

Registration date
03/09/2012

Overall study status
Completed

Last Edited
26/05/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A subarachnoid haemorrhage (SAH) is a type of stroke that is most often caused by a bulge in a brain blood vessel (aneurysm) bursting and bleeding into the subarachnoid space surrounding the brain. It is a life-threatening disease and those patients who survive the early bleeding are at risk of developing secondary complications such as delayed cerebral ischemia (DCI), a form of secondary stroke. In general, DCI is the major cause of poor outcome and death after SAH. One of the major contributors to DCI is the amount of blood in the subarachnoid space, and reducing the subarachnoid blood has been found to decrease DCI. Therefore the aim of this study is to assess the effect of blood clearance using a blood resolving agent (rt-PA) in patients with severe aneurysmal SAH.

Who can participate?
Patients aged over 18 with severe aneurysmal SAH

What does the study involve?
Participants are randomly allocated to one of two groups. One group is treated with rt-PA via a standard monitoring catheter (tube) into the brain chambers (ventricles) whilst being slowly rotated on a moving bed for 48 hours. The other group receives treatment as usual. Both groups are followed up to assess their neurological (mental) outcome and undergo CT scans to check for cerebral infarctions (brain damage).

What are the possible benefits and risks of participating?
By reducing the amount of blood in the subarachnoid space, DCI and poor neurological outcome may be prevented. One possible risk of rt-PA is an increased risk of bleeding in the brain (intracranial) or in the rest of the body (systemic). However, based on previous studies, the risk of side effects is very low.

Where is the study run from?
Heinrich-Heine University (Germany)

When is the study starting and how long is it expected to run for?
December 2008 to September 2011

Who is funding the study?
Heinrich-Heine University (Germany)

Who is the main contact?
Prof. Daniel Hänggi

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Study ID: 3062

Study information

Scientific Title
Prospective, randomized, phase IIb trial on concomitant intraventricular fibrinolysis and low-frequency rotation after severe subarachnoid hemorrhage

Study objectives
To test whether increased wash-out of subarachnoid blood by intraventrikular fibrinolysis and low-frequency rotation can reduce the incidence of secondary brain injury and poor outcome after aneurysmal subarachnoid hemorrhage (SAH).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Institutional Ethics Committee of the Medical Faculty of Heinrich-Heine University, 06/06/2008, ref: 3062

Study design
Single-center randomized controlled phase IIb study with blinded outcome analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Aneurysmal subarchnoid hemorrhage

Interventions
Concomitant intraventricular fibrinolysis (rt-PA) and low frequency rotational therapy for 48 hours, as compared to treatment as usal.

Experimental therapy consists of intraventricular application of recombinant tissue plasminogen activator (rt-PA, Actilyse®, Boehringer Ingelheim, Germany) and low frequency rotational therapy (RotoRest®, KCI, NY, USA). Experimental therapy is initiated 6 hours, after obliteration of the ruptured aneurysm and unremarkable postinterventional CT scan, and conducted for 48 hours. For intraventricular fibrinolysis, 5 mg of rt-PA will be diluted in 2ml of NaCl and given as an intraventicular bolus every 12 hours over 48 hours via the external ventricular drain. After rt-PA bolus, the external ventricular drain will be locked and solely used to monitor intracranial pressure for 30 minutes to avoid premature drainage of the fibrinolytic agent. During the 48-hour period patients will remain sedated and intubated with concomitant lateral rotational therapy. Daily CT scanning will be performed until 2 days after cessation of rt-PA fibrinolysis to rule out hemorrhagic complications. Patients will be monitored for DCI using Perfusion-CT scanning.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Glasgow outcome score at discharge and after 6 weeks

Secondary outcome measures
1. Clot clearance rate (CCR) between day 1 and day 5 after SAH ictus
2. Radiographic vasospasm between day 1 and day 15 after SAH ictus
3. New cerebral infarction on discharge CT or after death
4. Occurrence of posthemorrhagic hydrocephalus at discharge

Overall study start date
01/12/2008

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Aneurysmal SAH (WFNS grade III-V)
2. Fisher grade II - IV
3. Patient age > 18
4. Admission less than 24 hours after ictus
5. No history for anticoagulative or antiaggregative agents
6. Informed consent by a legal representative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Non-aneurysmal or Fisher ° 0-I SAH
2. Fusiform, mycotic or traumatic aneurysms
3. Pregnancy
4. Admission greater than 24 hours after ictus
5. History for severe cardiovascular disease
6. Clotting disorders
7. Platelet count less than 100,000, INR greater than 1.4
8. Ongoing internal bleeding

Date of first enrolment
01/12/2008

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Germany

Study participating centre
Heinrich-Heine University
Düsseldorf
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40225

Sponsor information

Organisation
Heinrich-Heine University (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.uni-duesseldorf.de/

ROR
https://ror.org/024z2rq82

Funder(s)

Funder type
University/education

Funder Name

Heinrich-Heine-Universität Düsseldorf

Alternative Name(s)
Heinrich Heine University Düsseldorf, HHU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No