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

Submission date 18/07/2012	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
		☐ Protocol		
Registration date 03/09/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 26/05/2017	Condition category Circulatory System	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

Prof Daniel Hänggi

#### Contact details

Department of Neurosurgery Heinrich-Heine University Moorenstr. 5 Düsseldorf Germany 40225

## Additional identifiers

#### Protocol serial number

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

## Study type(s)

Treatment

#### 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(s)

Glasgow outcome score at discharge and after 6 weeks

## Key secondary outcome(s))

- 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

## 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

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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 Germany 40225

# Sponsor information

#### Organisation

Heinrich-Heine University (Germany)

#### **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**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article01/08/2013YesNoParticipant information sheet11/11/202511/11/2025NoYes