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Intraventricular infusion of rt-PA in severe intraventricular haemorrhage after aneurysmal subarachnoid haemorrhage. A randomised clinical trial.

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/08/2009	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR455

Study information

Scientific Title
(Added 14/08/09) Recombinant tissue plasminogen activator (rt-PA) and external ventricular drain (EVD) in subarachnoid haemorrhage (SAH) with obstructive hydrocephalus for lysis of ventricular blood. A randomised clinical trial.

Acronym
RESOLVE

Study objectives
Intraventricular infusion of rt-PA reduces the frequency of poor outcome (death or dependency) in patients with a severe intraventricular haemorrhage after aneurysmal subarachnoid hemorrhage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Single centre prospective randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aneurysmal subarachnoid haemorrhage, Hydrocephalus, Intraventricular haemorrhage

Interventions
1. Placement of external ventricular drain (standard procedure)
2. Clipping/Coiling of ruptured aneurysm (standard procedure)
3. Infusion of rt-PA or placebo through external ventricular drain

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Death or dependency 6 months after subarachnoid haemorrhage

Key secondary outcome(s))
1. Recurrent haemorrhage
2. Secondary ischaemia
3. Hydrocephalus
4. Bleeding complications from fibrinolysis

5. Death within 6 months
6. Rankin 0 versus Rankin 1-5 and death

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. First or recurrent aneurysmal subarachnoid haemorrhage with intraventricular extension of the haemorrhage
2. The ventricles must be enlarged and the intraventricular haemorrhage must be severe (Graeb-score more than 6)
3. Patients must be in a poor neurological condition, WFNS <7 or WFNS <6 in intubated patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Other cause for intraventricular haemorrhage than a subarachnoid haemorrhage from a ruptured intracranial aneurysm
2. Absence of both pupillary light reflexes
3. Use of oral anticoagulants
4. Treating physicians propose a palliative instead of curative treatment strategy
5. Absence of informed consent

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Center Utrecht
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation
University Medical Center Utrecht, Department of Neurology (The Netherlands)

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Utrecht (UMCU) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration