

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/08/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Death or dependency 6 months after subarachnoid haemorrhage

Secondary outcome measures

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

Overall study start date

01/09/2005

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

16

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)

Sponsor details

Heidelberglaan 100

Utrecht

Netherlands

3584 CX

Sponsor type

Not defined

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Utrecht (UMCU) (Netherlands)

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