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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

Registration date
27/01/2006

Last Edited
14/08/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr D. Nieuwkamp

Contact details
University Medical Center Utrecht
Department of Neurology
Heidelberglaan 100
Utrecht
Netherlands
3584 CX
d.nieuwkamp@neuro.azu.nl

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