

Dutch Intraventricular Thrombolysis in Cerebral Haemorrhage study

Submission date 09/01/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 09/01/2006	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
NTR496

Study information

Scientific Title

Acronym

DITCH

Study objectives

In patients with intraventricular haemorrhage (IVH) caused by extension from an intracerebral haemorrhage (ICH), ventricular drainage combined with intraventricular thrombolysis improves three month outcome when compared to standard treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre randomised single blind active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intraventricular haemorrhage, intracerebral haemorrhage

Interventions

External ventricular drain(s) (EVD) placement. Infusion of 3 mg tr-PA through the EVD twice daily with a maximum of six days, compared to extraventricular drainage alone.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Poor outcome at three months (mRankin scale and GOS).

Key secondary outcome(s)

1. Drain dependency at 3 months
2. Amsterdam Linear Disability Scale score at 3 months
3. Intraventricular or parenchymal bleeding complications
4. Ventriculitis

Completion date

01/02/2008

Eligibility

Key inclusion criteria

1. Age >18 years
2. IVH caused by extension of spontaneous ICH confirmed by computed tomography (CT) scan
3. Glasgow Coma Score on admission of <14
4. Able to include patients within 48 hours after ICH onset
5. Historical mRankin of 0 or 1

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. IVH caused by aneurysm or arteriovenous malformation as seen on CT-scan
2. Only sedimentation of blood in the lateral ventricles
3. Infratentorial bleeding
4. Evacuation of parenchymal hematoma is deemed necessary
5. Clotting disorder
6. Pregnancy
7. Epileptic seizure at onset
8. Absence of brain stem reflexes on admission
9. If death appears imminent

Date of first enrolment

01/02/2006

Date of final enrolment

01/02/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

University/education

Funder Name

Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration