ISRCTN19105863 https://doi.org/10.1186/ISRCTN19105863

Dutch Intraventricular Thrombolysis in Cerebral Haemorrhage study

Submission date	Recruitment status	[X] Prospectively registered
09/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/08/2009	Circulatory System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

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

Overall study start date
01/02/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46

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)

Sponsor details
Department of Neurology
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Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Centre (AMC) (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