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# 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

**Contact name**
Dr K. Gans, de

**Contact details**
Academic Medical Center
Department of Neurology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5663842
K.deGans@amc.uva.nl

## 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