Dutch Intraventricular Trombolysis in Cerebral Haemorrhage study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20122

Source NTR

Brief title DITCH

Health condition

Intraventricular haemorrhage caused by extension of intracerebral haemorrhage.

Sponsors and support

Primary sponsor: Geen sponsor. Geinitieerd door de afdeling neurologie van het AMC Source(s) of monetary or material Support: n/a

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

Background - Intraventricular haemorrhage caused by extension from an intracerebral haemorrhage leads to acute hydrocephalus and often to poor outcome. Treatment consists of repeated lumbar puncture or extraventricular drainage but in case of massive intraventricular haemorrhage, repeated lumbar puncture is not an option and extraventricular drainage is often hampered by obstruction of the drain. Moreover, blood clotted drains very often cause ventricular infections also resulting in poor clinical outcome.

In recent years several studies have described intraventricular fibrinolytic treatment in combination with extraventricular drainage to prevent drain obstruction.

In a meta-analysis combining the results of these studies, intraventricular fibrinolytic treatment improved poor clinical outcome from 90% in patients with ventricular drainage without thrombolysis or no drainage at all to 34% in patients treated with intraventricular drainage with fibrinolytic treatment. However, none of the studies in this meta-analysis was randomised, all had an observational design and most included only very few patients. A randomised clinical trial is therefore warranted.

Hypothesis - In patients with intraventricular haemorrhage caused by extension from an intracerebral haemorrhage ventricular drainage combined with intraventricular thrombolysis improves three month outcome when compared to standard treatment.

Study objectives - To investigate whether ventricular drainage combined with intraventricular thrombolysis improves current outcome results in patients with intraventricular haemorrhage caused by extension from an intracerebral haemorrhage.

Methods - The study design is a multicentre randomised controlled clinical trial. Based on the power calculations this study will include 46 patients with intraventricular haemorrhage caused by extension from an intracerebral haemorrhage, 23 in the treatment group and 23 in the control group. With this number of patients we should be able to determine if the treatment is safe and effective.

Expected results - Based on the meta-analysis of the non-randomised studies we expect a reduction of poor outcome of 75% in the group treated with ventricular drainage combined with intraventricular thrombolysis.

Study objective

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

Intervention

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

Contacts

Public

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Eligibility criteria

Inclusion criteria

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

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2006
Enrollment:	46
Туре:	Anticipated

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Ethics review

Positive opinionDate:05-12Application type:First

05-11-2005 First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL455
NTR-old	NTR496
Other	: N/A
ISRCTN	ISRCTN19105863

Study results

Summary results

Nieuwkamp DJ, De Gans K, Rinkel GJE, Algra A. Treatment and outcome of severe intraventricular extension in patients with subarachnoid or intracerebral hemorrhage: a systematic review of the literature. Journal of Neurology 2000 247:117-121.