Dutch Intraventricular Trombolysis in Cerebral Haemorrhage study.

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20122

Bron
NTR

Verkorte titel
DITCH

Aandoening

Intraventricular haemorrhage caused by extension of intracerebral haemorrhage.

Ondersteuning

Primaire sponsor: Geen sponsor.
Geinitieerd door de afdeling neurologie van het AMC
Overige ondersteuning: n/a

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 18 years;

2. IVH caused by extension of spontaneous ICH confirmed by 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2006
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-11-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.