Intraventricular infusion of rt-PA in severe intraventricular haemorrhage after aneurysmal subarachnoid haemorrhage. A randomised clinical trial.

No registrations found.

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

Summary

ID

NL-OMON28831

Source
NTR

Brief title
RESOLVE

Health condition

Aneurysmal subarachnoid haemorrhage, hydrocephalus, intraventricular haemorrhage.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Death or dependency 6 months after subarachnoid haemorrhage.

Secondary outcome

1. Recurrent haemorrhage;
2. Secondary ischaemia;
3. Hydrocephalus;
4. Bleeding complications from fibrinolysis;
5. Death within 6 months;
6. Rankin 0 versus Rankin 1-5 and death.

Study description

Background summary

The Resolve study is a prospective randomized, placebo-controlled, monocenter trial to determine whether intraventricular infusion of rt-PA reduces the frequency of poor outcome (death or dependence) in patients with a severe intraventricular haemorrhage after aneurysmal subarachnoid hemorrhage.

Study objective

Intraventricular infusion of rt-PA reduces the frequency of poor outcome
(death or dependency) in patients with a severe intraventricular haemorrhage after aneurysmal subarachnoid hemorrhage.

Intervention

1. Placement of external ventricular drain (standard procedure);
2. Clipping / Coiling of ruptured aneurysm (standard procedure);
3. Infusion of rt-PA or placebo through external ventricular drain.

Contacts

Public
University Medical Center Utrecht (UMCU),
Department of Neurology,
Heidelberglaan 100
D. Nieuwkamp
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
Scientific

University Medical Center Utrecht (UMCU),
Department of Neurology,
Heidelberglaan 100
D. Nieuwkamp
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands

Eligibility criteria

Inclusion criteria

1. First or recurrent aneurysmal subarachnoid haemorrhage with intraventricular extension of the haemorrhage;
2. The ventricles must be enlarged and the intraventricular haemorrhage must be severe (Graeb-score more than 6);
3. Patients must be in a poor neurological condition, WFNS < 7 or WFNS < 6 in intubated patients.

Exclusion criteria

1. Other cause for intraventricular haemorrhage than a subarachnoid haemorrhage from a ruptured intracranial aneurysm;
2. Absence of both pupillary light reflexes;
3. Use of oral anticoagulants;
4. Treating physicians propose a palliative instead of curative treatment strategy;
5. Absence of informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2005
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-10-2005
Application type:	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	NL415
NTR-old	NTR455
Other	: N/A
ISRCTN	ISRCTN36786212

Study results

Summary results

N/A