Platelet Transfusion in Cerebral Haemorrhage

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The objective of our study is to investigate whether platelet transfusion within 6 hours after onset of ICH can improve functional outcome by limiting haematoma growth in patients using PAI.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON31663

Source
ToetsingOnline

Brief title
PATCH

Condition

- Central nervous system vascular disorders
- Vascular haemorrhagic disorders

Synonym
brain haemorrhage, intracerebral haemorrhage (ICH)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: haemorrhage, platelet, platelet aggregation inhibitor, stroke

Outcome measures

Primary outcome

- Three months after randomisation patients functional health outcome is scored on the modified Rankin Scale (mRS), poor outcome is defined as a score of 3-6.

Secondary outcome

- Haematoma growth: the difference in haematoma volume between the first CT-scan and a repeat scan after 24 hours (assessed by a radiologist blinded for treatment)
- Predictive value of PFA-100 test results regarding benefit from platelet transfusion
- Differences in PFA-100 results before and after platelet transfusion
- Percentage of patients with PFA-100 results in the Emergency Department within 30 minutes
- Predictive value of the CTA 'spot sign' regarding benefit from platelet transfusion
- Predictive value of the CTA "spot sign" regarding haematoma enlargement on CT
- Complications of platelet transfusion (thrombotic, infectious, transfusion reactions)
- Survival at 3 months
- Disability at 3 months using the AMC linear disability score (ALDS) assessed in telephone interview by trained research nurses, blinded for treatment allocation

- Patient*s functional health using the full ordinal scoring range of the

modified ranking scale at 3 months

- Poor outcome at 3 months defined as a mRS score of 3-6

- Cause of poor outcome assessed by a Classification Committee of experienced

neurologists

- Costs

Study description

Background summary

Stroke is a major cause of acquired disability in the Netherlands. After the care for children born with a handicap, the care for stroke patients consumes the largest portion of the total health care budget.
In recent years acute treatment in ischemic stroke improved significantly. Thrombolysis within 3 hours was shown to improve clinical outcome. However, for haemorrhagic stroke or intracerebral haemorrhage (ICH), which accounts for 15% of all stroke patients, no acute treatment option currently exists.
Haematoma volume is one of the most important outcome predictors in ICH. Because several studies have shown that haematoma volume increases during the first 6 hours after onset of ICH, reduction of this haematoma growth provides a promising target to improve outcome. Patients using platelet aggregation inhibitors (PAI) are especially at risk for haematoma growth and therefore platelet transfusion (PT) is an acute treatment option which should be investigated.

Study objective

The objective of our study is to investigate whether platelet transfusion within 6 hours after onset of ICH can improve functional outcome by limiting haematoma growth in patients using PAI.

Study design

Multicenter study in 30 Dutch hospitals.
Probe: Prospective, Randomised, Open treatment, Blind End-point evaluation

Intervention

Patients are randomised to receive a single gift of platelets (5 or 10 donor units) within 6 hours after start of symptoms or standard care without platelet transfusion.

Study burden and risks

The extra burden for the patients consists of one CT scan of the brain and in selected centres a CT angiography of the cerebral circulation. A blood sample will be collected two times to measure platelet function.
The risk for patients receiving platelet transfusion consists of transfusion reactions. There is a 1-6% chance of experiencing such a reaction. Most transfusion reactions are harmless. In less than 0.1% the reaction is serious.
The expected risk of thrombo-embolic complications in patients without thrombocytopenia is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age 18-75 years
- Patients with non-traumatic, supratentorial ICH confirmed by CT
- Haematoma volume < 150 cc
- Glagow Coma Scale score 8-15
- Platelet aggregation inhibitors used at least seven days preceding haemorrhage
- Treatment can be initiated within 6 hours after onset of first signs and within 1* hours of the CT scan
- Pre-stroke Rankin scale score 0 or 1 (No symptoms, No significant disability despite symptoms; able to carry out all usual duties and activities)

Exclusion criteria

- Haematoma on CT compatible with epidural, subdural, aneurysmal or arterio-venous malformation (AVM) haematoma
- Planned surgical evacuation of haematoma within 24 hours after admission
- Presence of intraventricular blood if more than sedimentation in the posterior horns of the lateral ventricles
- Previous adverse reaction after platelet transfusion
- Previously legally incompetent adults
- Death appears imminent
- Known use of vitamin K antagonists (unless INR < 1.3)
- Known thrombocytopenia < 100 x 10E9/l
- History of coagulopathy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	190
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28517
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL16450.018.08
OMON	NL-OMON28517