Platelet transfusion in brain haemorrhage

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Platelet transfusion limits haematoma growth and thus improves outcome in patients with intracerebral haemorrhage using anti-platelet therapy.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28517

Bron
Nationaal Trial Register

Verkorte titel
PATCH

Aandoening

Intracerebraal hematoom
CVA
Beroerte
Trombocyten transfusie

Intracerebral haemorrhage
Stroke
Platelet transfusion
Anti-platelet therapy

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: ZonMw
Sanquin

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Poor outcome defined as a modified Rankin Scale (mRS) score 4-6 after 3 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Platelet Transfusion in Cerebral Haemorrhage (PATCH)

Background

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.

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

Probe: Prospective, randomised, open treatment, blind end-point evaluation

Study Population

Patients with spontaneous ICH who were using PAI at least during the 7 days preceding haemorrhage.

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

Outcome

The primary endpoint is poor functional outcome as recorded on the modified Rankin Scale (mRS) at three months follow-up (mRS 4-6).

Secondary endpoints are complications of PT, haematoma enlargement on CT-scan, survival at three months, changes in outcome at three months (analysis of the mRS score as an ordinal scale), poor outcome defined as mRS 3-6, disability assessed with the ALDS scale, cause of poor outcome, costs and predictive value of the CTA 'spot sign' and different laboratory measurements.

Sample Size

Poor outcome occurs in at least 70% of these patients. To detect a reduction of poor outcome from 70% to 50% with a two group Chi-square test with a 0.05 two-sided significance level and 80% power, 95 patients are needed in each group (190 patients in total).

Thirty centers are willing to participate in our study. If each center can randomize 3 to 4 patients each year, patient inclusion will be completed in 21 months. The last patient will then be assessed 2 years after the onset of the study.

Doel van het onderzoek

Platelet transfusion limits haematoma growth and thus improves outcome in patients with intracerebral haemorrhage using anti-platelet therapy.

Onderzoeksopzet

Primary outcome will be determined after 3 months.

Onderzoeksproduct en/of interventie

- 95 patients receive platelet transfusion as soon as possible within 6 hours after onset

- 95 patients receive standard care

Platelet transfusion consists of a single gift of 5 or 10 donor units depending on type of anti-platelet medication (only patients using clopidogrel receive 10 units).

Contactpersonen

Publiek

Department of Neurology

Academic Medical Center

University of Amsterdam

Irem Baharoglu
PO BOX 22660

Amsterdam 1100 DD
The Netherlands

Wetenschappelijk

Department of Neurology

Academic Medical Center

University of Amsterdam

Irem Baharoglu
PO BOX 22660

Amsterdam 1100 DD
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 18 years

2. Non-traumatic, primary, supratentorial ICH

3. Haematoma volume > 150 cc

4. GCS score 8-15

5. Anti-platelet therapy for at least the previous 7 days

6. Transfusion can be started < 6 hrs after onset

7. Transfusion can be started < 1,5 hrs after CT

8. mRankin scale score before ICH 0 or 1

9. Informed consent obtained

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Bleeding pattern on CT suggestive of AVM or aneurysm

2. Haematoma evacuation planned < 24 hrs

3. Intraventricular haemorrhage (sedimentation in posterior horns is allowed)

4. Previous adverse reaction to platelet transfusion

5. Known use of vitamine K antagonists

6. Known thrombocytopenia < 100 x 109/l

7. History of coagulopathy

8. Previously legally incompetent adults prior to stroke

9. Death appears imminent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	190
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-04-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 31663
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1257
NTR-old	NTR1303
CCMO	NL16450.018.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON31663

Resultaten

Samenvatting resultaten
N/A