Efficacy of Transfusions with platelets stored in platelet additive solution II versus plasma.

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Utilization of platelets stored in additive solutions has several advantages. A former RCT testing platelets stored in platelet additive solution II versus plasma excluded patients with factors of increased platelet consumption. In this study also...

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

Samenvatting

ID

NL-OMON26192

Bron
NTR

Verkorte titel
platelet transfusions and efficacy

Aandoening

1. Hemato-oncological patients;

2. Thrombocytopenia.

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1- and 24-hour corrected count increment.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Utilization of platelet additive solutions (PASs) for storage of platelets has several advantages, however randomised studies testing the clinical efficacy are scarce.
A prospective, randomised study comparing the efficacy of transfusions with platelets stored in Platelet Additive Solution II (PAS II) versus plasma showed that CCIs after transfusion with platelets stored in PAS II were significantly lower (1). Major drawbacks of this study were the exclusion of patients with clinical factors known to increase platelet consumption and a limited number of patients.

A multicenter, randomised study to investigate clinical efficacy of platelets stored in PAS II versus plasma, also including patients with factors of increased platelet consumption, was performed.

Methods:

After consent patients > 18 years, without HLA- and/or HPA-alloantibodies, were randomised to receive pooled platelet concentrates (PC) suspended in either plasma or PAS II, leucoreduced, and stored up to 5 days. 1- and 24-hour CCI were the primary endpoints.

Secondary endpoints were transfusion interval, adverse reactions and bleeding complications.

An inclusion-period was defined as a maximum of 8 transfusions or 30 days after the first transfusion.

Doel van het onderzoek

Utilization of platelets stored in additive solutions has several advantages. A former RCT testing platelets stored in platelet additive solution II versus plasma excluded patients with factors of increased platelet consumption.

In this study also this category of patients are included and we expect to find differences in outcome, as compared to the previous study.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Platelet transfusion, trigger based.

Contactpersonen

Publiek

HagaHospital,
Leyweg 275
J.L.H. Kerkhoffs
Den Haag 2545 CH
The Netherlands
+31 (0)70 3592004

Wetenschappelijk

HagaHospital,
Leyweg 275
J.L.H. Kerkhoffs
Den Haag 2545 CH
The Netherlands
+31 (0)70 3592004

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients > 18 years expected to receive platelet transfusions.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

HLA- and/or HPA allo-immunization.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2003
Aantal proefpersonen:	195
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
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	NL258
NTR-old	NTR296
Ander register	: P03.113
ISRCTN	ISRCTN52543592

Resultaten

Samenvatting resultaten
Blood. 2006 Nov 1;108(9):3210-5. Epub 2006 Jul 6.