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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26192

Source
NTR

Brief title
platelet transfusions and efficacy

Health condition

1. Hemato-oncological patients;

2. Thrombocytopenia.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

1- and 24-hour corrected count increment.

Secondary outcome

1. Bleeding complications;

2. Transfusion reactions;

3. Transfusion interval.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

Platelet transfusion, trigger based.

Contacts

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Eligibility criteria

Inclusion criteria

Patients > 18 years expected to receive platelet transfusions.

Exclusion criteria

HLA- and/or HPA allo-immunization.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2003
Enrollment:	195
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
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	NL258
NTR-old	NTR296
Other	: P03.113
ISRCTN	ISRCTN52543592

Study results

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