Clinical effectiveness and safety of pooled, random donor platelet concentrates, leucoreduced and stored up to seven days either in additive solution with and without pathogen reduction or plasma in hemato-oncological patients.
(The TriPlate study)

Published: 22-01-2007
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To assess the non-inferiority of PAS III-PC and PR-PAS III-PC compared to plasma-PC in terms of recovery, estimated by the 1-hour CCI post transfusion.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON30251

Source
ToetsingOnline

Brief title
HOVON 82

Condition

- Leukaemias

Synonym

thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: HOVON
Source(s) of monetary or material Support: stichting HOVON en Sanquin

Intervention

Keyword: hemato-oncological, platelet products, thrombocytopenia, transfusion

Outcome measures

Primary outcome

1- hour CCI

Secondary outcome

- 24-hour CCI

- Bleeding grade 2 and higher

- Transfusion requirement, red cells and platelets

- Platelet transfusion interval

- Adverse transfusion reactions

Study description

Background summary

Extending storage for logistic purposes, combined with maintaining or even improving the safety of platelet products, and maintaining clinical efficacy are the main features in the development of new platelet products. In this study protocol we aim to investigate transfusion efficacy of three different platelet products: Plasma-PC, PAS III-PC and PR-PAS III-PC, combining extended storage and the use of an additive solution, with or without treatment with a photochemical pathogen reduction technique. Prior to the start of the clinical study an in vitro study has been performed, showing that all study products meet the minimal quality requirements. Both 1- and 24-hour CCI are commonly

used to evaluate platelet transfusions and, albeit not without discussion, currently they are the only parameters in trigger based transfusion policies. Refractoriness to platelet transfusions and bleeding complications are the main clinical problems in intensively treated hemato-oncological patients and are essential endpoints for transfusion studies.

Study objective

To assess the non-inferiority of PAS III-PC and PR-PAS III-PC compared to plasma-PC in terms of recovery, estimated by the 1-hour CCI post transfusion.

Study design

The study is a prospective, randomized multicenter trial for the evaluation of platelet products in hemato-oncological patients with thrombocytopenia or expected to become thrombocytopenic caused by myelosuppressive therapy or hemato-oncological related myelosuppression. In this trial patients will be randomized to receive one of three platelet products during one transfusion period:

Arm A: Plasma stored platelet concentrates (Plasma-PC)

Arm B: PAS III stored platelet concentrates (PAS III-PC)

Arm C: Pathogen reduced PAS III stored platelet concentrates (PR-PAS III-PC)

Intervention

In this trial patients will be randomized to receive one of three platelet products during one transfusion period:

Arm A: Plasma stored platelet concentrates (Plasma-PC)

Arm B: PAS III stored platelet concentrates (PAS III-PC)

Arm C: Pathogen reduced PAS III stored platelet concentrates (PR-PAS III-PC)

Study burden and risks

absence (no other than the usual risks associated with platelet transfusions)

Contacts

Public

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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 years.
- Expected * 2 platelet transfusion requirements.
- Written informed consent.
- Having a hemato-oncological disease

Exclusion criteria

- Known immunological refractoriness to platelet transfusions, i.e. HLA- and/or HPA-allo immunization and/or clinical relevant auto-antibodies.
- Pregnancy (or lactating)
- Previous inclusion in this study

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2007
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL14989.098.06