Recovery and survival of platelets in additive solution

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24088

Source
Nationaal Trial Register

Brief title
RaSPAS study

Health condition

Hemato oncologic disease; myelodysplastic syndrome; platelets; plasma; additive solution; recovery; survival

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: nvt

Intervention

Outcome measures

Primary outcome

Platelet recovery in the study groups should be ≥67% of platelets in plasma stored for 2-3

days.

Secondary outcome

o Phase 2: To determine the recovery and survival of platelet concentrates in Composol, Intersol and SSP+ (in a ±35%-plasma/±65%-PAS ratio) stored for 6-7 days.

o To determine survival of platelet concentrates, stored for 2-3 (plasma only) or 6-7 days in plasma, Composol, Intersol and SSP+ (in a ±35%-plasma/±65%-PAS ratio).

o To determine the 1-h and 24-h count increment and corrected count increment of platelet concentrates, stored for 2-3 (plasma only) or 6-7 days in plasma, or in Composol, Intersol and SSP+ (in a ±35%-plasma/±65%-PAS ratio).

Study description

Background summary

Platelets in plasma can be stored for at least 7 days under blood bank conditions with maintenance of in vitro and in vivo quality. The use of platelet additive solution (PAS) as replacement for storage in plasma is attractive, as PASs are associated with about 50% fewer allergic reactions post transfusion. Further, there is evidence that the newer generation PASs have much better capability of maintaining the platelet quality, and are thought to be at least equal to that in plasma. A number of alternative PASs are available (for example Composol, Intersol and SSP+); not only do they preserve the platelet function better, they also provide a margin in case safety technologies (like pathogen reduction methods) are applied that would potentially reduce platelet shelf life.

The objectives of this study is to determine the recovery and survival of platelet concentrates;

in the first phase, a comparison will be made for platelet concentrates in plasma stored for 2-3

days versus those stored for 6-7 days; in the second phase, platelet concentrates stored for

6-7

days in Composol, Intersol and SSP+ (in about a 35%-plasma/65%-PAS ratio) will be

evaluated.

Study objective

The recovery and survival of platelets stored in 3 different platelet additive solutions for 7 days is non inferior to the recovery and survival of platelets stored in plasma for 7 days

Intervention

The standard of care in the Netherlands is 7 day storage of platelet concentrates in plasma or

in Intersol platelet additive solution (PAS). The intervention is that patients will receive

platelet concentrates in newer PASs, stored for 6-7 days.

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18 years.

• Expected to require at least one platelet transfusion.

• Signed informed consent.

• Are hospitalized.

• Clinically stable, i.e. no active bleeding, no fever, or other reasons for increased platelet consumption.

• Have acute leukemia or MDS.

Exclusion criteria

• Micro-angiopathic thrombocytopenia (TTP, HUS) and ITP.

• Bleeding grade 2 at time of inclusion.

• Transfusions within 1 week after ATG

• Known immunological refractoriness to platelet transfusions.

• HLA- and/or HPA-allo immunization and/or clinically relevant auto-antibodies.

• Indications to use platelet concentrates with specific characteristics/modifications.

• Pregnancy (or lactating).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	04-05-2015
Enrollment:	0
Type:	Unknown

Ethics review

Positive opinion

Date:	25-03-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41726
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4875
NTR-old	NTR5146
CCMO	NL49911.098.14
OMON	NL-OMON41726

Study results