Recovery and survival of platelet concentrates in plasma and in 3 additive solutions

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Platelet disorders
Study type	Interventional

Summary

ID

NL-OMON41726

Source
ToetsingOnline

Brief title
RaSPAS study

Condition

- Platelet disorders

Synonym
bleeding, Thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Meander Medisch Centrum;Sanquin Bloedbank

Intervention

Keyword: Platelet additive solution, Platelet storage

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.

Secondary Objective(s):

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.

Study objective

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 design

The recovery and survival of these platelets will be determined in patients with acute leukemia or MDS. Platelet concentrates in plasma and stored for 2-3 or 6-7 days; or made with one of the PASs mentioned above, will be administered to the patient if the transfusion trigger is met. Donor platelets have HLA antigens that are usually different from the patient*s platelets, and the various populations can be tracked using fluorescent-labeled anti HLA antibodies, with subsequent detection using flow cytometry. Based on a 60% recovery after transfusion for *fresh* platelets, an absolute allowed difference of 20%, a standard deviation of 10%, with alpha=0.05 and a power of 90%, 7 transfusions for each of the study conditions need to be performed in consenting non-alloimmunized thrombocytopenic patients.
In addition, recovery and survival will be determined using differences in the highly variable regions of mitochondrial DNA. Differences will be determined with a Ligation Detection Reaction.

Intervention

The standard of care in the Netherlands is 7 day storage of platelet concentrates in plasma or in Intersol. The intervention is that patients will receive in newer PASs, stored for 6-7 days.

Study burden and risks

Patients will undergo up to 5 blood samplings in addition to regular sampling. Preferably, sampling is performed using a katheter, which is usually present in this patient group. Patients may need to be transfused at a higher platelet count as the current trigger (a platelet concentration below 10 x10^9/L), up to a trigger of 20 x10^9/L. Under the worst circumstances the recovery and survival of the platelets are zero, thus the patients will require a new

transfusion. This potentially increases donor exposure of the patient. The only expected immediate benefit is a lower risk of allergic reactions. The risk of a study transfusion should be weighed in the light of all the transfusions a particular patient will receive.

Contacts

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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 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 (myelodysplastic syndrome).

Exclusion criteria

* Micro-angiopathic thrombocytopenia (TTP, HUS) and ITP.
* Bleeding greater than grade 2 at time of inclusion. If the patient has been treated for the bleeding complication, the patient can be included in the study 1 week after the last intervention that was used to stop the bleeding. Pre-existing skin bleeds (bruises) greater than 2.5 cm will not be included in judgment of the WHO bleeding grade at the time of assessment of eligibility or at the time of inclusion.
* Transfusions within 1 week after ATG.
* Known immunological refractoriness to platelet transfusions. Refractoriness may be known to the treating physician by either HLA/HPA antibody screening, or by earlier poor responses to platelet responses.
* HLA- and/or HPA-allo immunization and/or clinical relevant auto-antibodies.
* Indications to use platelet concentrates with specific characteristics/modifications (for example, volume reduced platelets, HLA matched platelets, etc).
* Pregnancy (or lactating).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO Date:	21-04-2015
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

ID: 24088
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49911.098.14
OMON	NL-OMON24088