Assessment of Buffy Coat Dosage

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23468

Source
Nationaal Trial Register

Brief title
Alphabet Study

Health condition

Hemato-oncologic

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Sanquin Blood Supply

Intervention

Outcome measures

Primary outcome

Percentage of days with grade 1b+2 bleeding according to the Bleeding Severity Measurement Scale (BSMS) as primary endpoint.

Secondary outcome

• total number of platelets received
• total number of individual buffy coats received

• the 1 and 24 hour CI
• the 1 and 24 hour CCI
• percentage of patients with at least one bleeding grade 1b+2 according to the BSMS
• percentage of patients and percentage of days per patient with at least one ≥ clinically relevant minor bleeding grade according to the ISTH bleeding scale
• rate of HLA alloimmunization
• adverse transfusion reactions
• platelet transfusion interval
• total number of platelet transfusions
• total number of red cell and plasma transfusions
• association between albumin/creatinine in urine and/or CRP and clinically relevant bleeding grades according to the BSMS
• cost benefit analysis

Study description

Background summary

Rationale: Studies have shown that hemato-oncologic patients with hypoproliferative thrombocytopenia can be supported with lower platelet doses than the current standard. The bleeding frequency was not different in patients treated with lower doses compared to the control group, while the overall platelet dose and donor exposure were lower. This is potentially beneficial as this may prevent antibody formation leading to platelet refractoriness, which is a condition where the patient does not respond to platelet transfusions. The earlier studies were performed with apheresis platelet concentrates from one donor. In Europe, platelet concentrates are derived from pooling buffy coat from multiple blood donations. The current standard is a pool from five buffy coats (5-BC-PCS), and we aim to investigate the clinical effectiveness of a pool of three buffy coats (3-BC-PCs). For these pooled products, we want to demonstrate that lower doses do not result in more bleeding. Further, we aim to explore whether alloimmunization and refractoriness when using a pooled platelet product is lower when three rather than five buffy coats are used.
Objective: To demonstrate non-inferiority of 3-BC-PCs versus 5-BC-PCs with grade 1b+2 bleeding according to the Bleeding Severity Measurement Scale (BSMS) as primary endpoint.
Study design: A prospective, randomized, open blinded endpoint, multicenter study.
Study population: Hemato-oncologic patients of at least 18 years of age, expected to receive at least two platelet transfusions during current hospitalization.
Intervention: The study group will receive 3-BC-PCs, the control group 5-BC-PCs.
Main study parameters/endpoints: The main study parameter is the percentage of days with bleeding grade 1b+2 according to the BSMS during a transfusion episode.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in the study group are expected to receive more transfusions, which is burdensome. Further, the patient will undergo daily assessment of bleeding symptoms, while some extra blood and urine samples need to be collected. The overall platelet dose is expected to be lower, reducing donor exposure and diminishing the risk of alloimmunization

and refractoriness, which is an immediate benefit for the patient. There is likely no immediate benefit for patients in the control group. These inconveniences and risks are considered to be relatively small for this group of hospitalized patients.

Study objective

To demonstrate non-inferiority of 3-BC-PCs versus 5-BC-PCs.

Study design

Daily after randomization, and ends maximally 6 weeks after the first platelet transfusion, or earlier for one of the following reasons: patient is no longer thrombocytopenic (> 7 days without requiring a platelet transfusion), hospital discharge, death or request by the patient to discontinue.

Intervention

The study group will receive 3-BC-PCs, the control group 5-BC-PCs.

Contacts

Public
HagaZiekenhuis
Pieter van der Meer

0612983735
Scientific
HagaZiekenhuis
Pieter van der Meer

0612983735

Eligibility criteria

Inclusion criteria

• Age ≥ 18 years.
• Having a hemato-oncologic disease.
• Expected ≥ 2 platelet transfusion requirements during current hospitalization.
• Signed informed consent.

Exclusion criteria

• Known immunological refractoriness to platelet transfusions.
• HLA- and/or HPA-alloimmunization and/or clinical relevant auto-antibodies.
• Indications to use HLA-typed platelet concentrates.
• Indications to use hyper-concentrated (plasma-reduced) platelet concentrates, for example patients with known severe allergic reactions or transfusion-associated circulatory overload (TACO).
• Micro-angiopathic thrombocytopenia (TTP, HUS) and ITP.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	520
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9204
Other	METC Leiden-Den Haag-Delft : P21.005

Study results