Assessment of Buffy Coat Dosage

Gepubliceerd: 19-01-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23468

Bron
Nationaal Trial Register

Verkorte titel
Alphabet Study

Aandoening

Hemato-oncologic

Ondersteuning

Primaire sponsor: HagaZiekenhuis
Overige ondersteuning: Sanquin Blood Supply

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	520
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9204
Ander register	METC Leiden-Den Haag-Delft : P21.005

Resultaten