The PREPAReS Study: Pathogen Reduction Evaluation & Predictive Analytical Rating Score.

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Non-inferiority (defined as < 12.5% increase) of pooled buffy coat-derived PR platelet concentrates (PR-plasma-PCs) compared to plasma (plasma-PCs) in terms of clinical efficacy determined by WHO grade ≥ 2 bleeding complications.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21216

Bron
Nationaal Trial Register

Verkorte titel
The PREPAReS Study: Pathogen Reduction Evaluation & Predictive Analytical Rating Score

Aandoening

Bleeding Grade 2-4
transfusion
pathogen reduction
thrombocytes

Ondersteuning

Primaire sponsor: CaridianBCT Biotechnologies LLC
Sanquin Blood supply
Overige ondersteuning: TerumoBCT

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

WHO grade ≥ 2 bleeding complications of PCs.

Toelichting onderzoek

Achtergrond van het onderzoek

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 malignancy-related myelosuppression. In this trial patients will be randomized to receive one of two platelet products during a transfusion episode with a maximum of 6 weeks.

Because the Mirasol-treated platelet products show a color difference not allowing an appropriate placebo, the study will be single-blinded for investigators evaluating the bleeding score.

Products will be stored up to 7 days. The primary endpoint is restricted to 5 days storage as this implies the most relevant information. Secondary endpoint evaluation requires that the patient continues treatment in the assigned study arm.

Arm A: Plasma stored platelet concentrates (Plasma-PCs);

Arm B: Pathogen reduced plasma-stored platelet concentrates (PR-plasma-PCs).

20-01-2013: In accordance with the METC, some changes have been accepted:
WHO bleeding scale is used to allow comparison with other trials in the area of platelet transfusion.

Doel van het onderzoek

Non-inferiority (defined as < 12.5% increase) of pooled buffy coat-derived PR platelet concentrates (PR-plasma-PCs) compared to plasma (plasma-PCs) in terms of clinical efficacy determined by WHO grade ≥ 2 bleeding complications.

Onderzoeksopzet

Prior to, and 1 hr and 24 hr after PC-transfusion.

Onderzoeksproduct en/of interventie

1. Pooled buffy coat-derived pathogen reduced platelet concentrates (PR-plasma-PCs), or;

2. Plasma (plasma-PCs), stored for 1-7 days.

Time of intervention has a maximum of 6 weeks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18 years;

2. Expected ≥ 2 platelet transfusion requirements;

3. Signed informed consent;

4. Having hemato oncological disease including those who undergo myelo ablative allogeneic stem cell transplant therapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Bleeding > grade 2 at randomization (after treatment, the patient can be randomized in the study after 2 or more weeks after the last transfusion that was used to stop the bleeding);

3. Known immunological refractoriness to platelet transfusions;

4. HLA- and/or HPA-allo immunization and/or clinical relevant auto-antibodies;

5. Indications to use hyper-concentrated (plasma-reduced) platelet concentrates, i.e. patients with known severe allergic reactions and documented transfusion-associated circulatory overload (TACO);

6. Pregnancy (or lactating);

7. Prior treatment with pathogen-reduced blood products;

8. Known allergy to riboflavin or its photoactive products.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	618
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-11-2009
Soort:	Eerste indiening

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	NL1989
NTR-old	NTR2106
Ander register	- : ABR30643
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A