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

No registrations found.

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

Summary

ID

NL-OMON21216

Source
NTR

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

Health condition

Bleeding Grade 2-4
transfusion
pathogen reduction
thrombocytes

Sponsors and support

Primary sponsor: CaridianBCT Biotechnologies LLC
Sanquin Blood supply
Source(s) of monetary or material Support: TerumoBCT

Intervention

Outcome measures

Primary outcome

WHO grade ≥ 2 bleeding complications of PCs.

Secondary outcome

Using PCs, stored for 1-7 days:

1. The 1 and 24 hour CI;

2. The 1 and 24 hour CCI;

3. (1+24 hour CCI)/2;

4. Adverse transfusion reactions;

5. Total transfusion requirement of red cells and platelets;

6. Platelet transfusion interval;

7. Rate of HLA allo-immunization;

8. In vitro quality markers related with the 1-hour or 24-hour CCI;

9. Clinical factors interacting on primary endpoint, including in vivo variables of immunological responses and of hemostasis in the recipients after transfusion as compared prior to transfusion.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
HagaHospital,
Leyweg 275
J.L.H. Kerkhoffs
Den Haag 2545 CH
The Netherlands
+31 (0)70 3592004
Scientific
HagaHospital,
Leyweg 275
J.L.H. Kerkhoffs
Den Haag 2545 CH
The Netherlands
+31 (0)70 3592004

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	618
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-11-2009
Application type:	First submission

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

Study results

Summary results
N/A