Clinical effectiveness of standard versus pathogen-reduced buffy coat-derived platelet concentrates in plasma in hemato-oncological patients;Pathogen Reduction Evaluation & Predictive Analytical Rating Score (The PREPAReS Study)

Published: 30-07-2010
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A prospective randomized phase III clinical trial to study the effectiveness of pathogen-reduced platelet concentrates in plasma, stored for up to 7 days, and compare these with untrested platelet concentrates in plasma, stored for up to 7 days. The...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Platelet disorders
Study type	Interventional

Summary

ID

NL-OMON43833

Source
ToetsingOnline

Brief title
The PREPAReS Study

Condition

- Platelet disorders
- Vascular haemorrhagic disorders

Synonym

bleeding, Thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin bloedvoorziening
Source(s) of monetary or material Support: TerumoBCT

Intervention

Keyword: Bleeding grade 2-4, pathogen reduction, platelets, transfusion

Outcome measures

Primary outcome

bleeding

Secondary outcome

platelet increments after transfusion, including correction for the body

surface area

percentage days with bleeding

transfusion reactions

number of red cell transfusions and platelet transfusions

number of days between transfusions

percentage of patients that develop antibodies

relation between laboratory tests and clinical outcomes

clinical factors that have an interaction with blood coagulation

Study description

Background summary

A new method was developed for pathogen-reduction of platelet concentrates to

inactivate micro-organisms that might be present. Riboflavin (vitamin B2) is added to the platelet concentrate, and then illuminated with UV-B, and is then ready for use. There are few clinical data on these treated platelet concentrates, and thus a clinical study is needed.
In this two-armed study, treated platelet concentrates are compared with untreated ones. From these platelet concentrates a sample will be taken immediately before issuing to the hospital, and various in vitro tests will be performed to link laboratory results with clinical outcomes. another objective is to study the possiblity that the treatment will result in less alloimmunization, which in turn will result in fewer patients that become unresponsive to platelet transfsions. In the hospital, the bleeding rate, increments after transfusion, and adverse events will be compared.

Study objective

A prospective randomized phase III clinical trial to study the effectiveness of pathogen-reduced platelet concentrates in plasma, stored for up to 7 days, and compare these with untrested platelet concentrates in plasma, stored for up to 7 days. The primary endpoint is bleeding greater than WHO grade 2 from platelet concentrates that were stored between 1 and 5 days.

Study design

single blinded, prospective, randomized phase III trial with 2 study arms

Intervention

one group of patients will receive platelet concentrates that have been pathogen-reduced, the other group will receive standard (untreated) platelet concentrates

Study burden and risks

small to none, the study closely relates to the current treatment of this patient group

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 * 2 platelet transfusion requirements.
* Having a hemato-oncological disease

Exclusion criteria

* Micro-angiopathic thrombocytopenia (TTP, HUS) and ITP
* 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)
* Known immunological refractoriness to platelet transfusions.
* HLA- and/or HPA-allo immunization and/or clinical relevant auto-antibodies.
* Indications to use hyper-concentrated (plasma-reduced) platelet concentrates, i.e. patients with known severe allergic reactions and documented transfusion-associated circulatory overload (TACO)
* Pregnancy (or lactating)
* Prior treatment with pathogen-reduced blood products
* Known allergy to riboflavin or its photoactive products

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-03-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-09-2011

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	13-10-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	03-04-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	29-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	13-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	19-12-2013

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-07-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-12-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-07-2016
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT2106
CCMO	NL30643.098.09