Efficacy of transfusions with platelets stored in platelet additive solution II versus plasma

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/12/2005		Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/12/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/12/2007	Signs and Symptoms			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr J.L.H Kerkhoffs

Contact details

Leyenburg Hospital,
Department of Hematology,
P.O. Box 40551
Den Haag
Netherlands
2504 LN
JeanLouis.Kerkhoffs@bloodrtd.nl

Additional identifiers

Protocol serial number

P03.113

Study information

Scientific Title

A multicenter randomised study of the efficacy of transfusions with platelets stored in platelet additive solution II versus plasma

Study objectives

Utilisation of platelets stored in additive solutions has several advantages. A former Randomised Controlled Trial (RCT) testing platelets stored in platelet additive solution II versus plasma excluded patients with factors of increased platelet consumption. In this study also this category of patients are included and we expect to find differences in outcome, as compared to the previous study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study protocol was approved by the Leiden University Medical Center and HagaZiekenhuis ethics committees and conducted according to the Guidelines of Good Clinical Practice.

Study design

Multicentre, randomised, double blinded, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Platelet transfusion

Interventions

Platelet transfusion, trigger based.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1- and 24-hour corrected count increment.

Key secondary outcome(s))

- 1. Bleeding complications
- 2. Transfusion reactions
- 3. Transfusion interval

Completion date

30/04/2005

Eligibility

Key inclusion criteria

Patients greater than 18 years expected to receive platelet transfusions.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

HLA- and/or HPA allo-immunisation

Date of first enrolment

01/10/2003

Date of final enrolment

30/04/2005

Locations

Countries of recruitment

Netherlands

Study participating centre Leyenburg Hospital,

Den Haag Netherlands 2504 LN

Sponsor information

Organisation

Leyenburg Hospital (The Netherlands) - Department of Hematology

ROR

https://ror.org/03q4p1y48

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/11/2006		Yes	No