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

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Platelet transfusion

Interventions
Platelet transfusion, trigger based.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1- and 24-hour corrected count increment.

Secondary outcome measures
1. Bleeding complications
2. Transfusion reactions
3. Transfusion interval

Overall study start date
01/10/2003

Completion date
30/04/2005

Eligibility

Key inclusion criteria
Patients greater than 18 years expected to receive platelet transfusions.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
195

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

Sponsor details
P.O. Box 40551
Den Haag
Netherlands
2504 LN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03q4p1y48

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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