

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/12/2007	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

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
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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