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Clinical effectiveness and safety of pooled, random donor platelet concentrates, leukoreduced and stored up to seven days either in additive solution with and without pathogen reduction or plasma in haemato-oncological patients

Submission date
08/02/2007

Recruitment status
No longer recruiting

Registration date
08/02/2007

Overall study status
Completed

Last Edited
02/09/2008

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hovon.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HO82; NTR861

Study information

Scientific Title

Acronym
HOVON 82

Study objectives
Platelet additive solution platelet concentrates (PAS III-PC) and pathogen reduced (PR)-PAS III-PC are non-inferior compared to plasma platelet concentrates (Plasma-PC) in terms of recovery, estimated by the one-hour corrected count increments (CCI) post-transfusion.

Secondary objectives:
1. To assess the effectiveness in relation to storage time of the used platelet product
2. To evaluate whether clinical factors interact with the different study products leading to a difference in platelet refractoriness
3. To assess the 24-hour CCI
4. To assess the safety (bleeding complications and adverse transfusion reactions)
5. To assess transfusion requirement (red cells and platelets)
6. To assess the transfusion interval

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (METC Zuidwest Holland) on the 22nd January 2007 (ref: METC protocol-nr 06-094) (ref. of approval letter: 2007-054).

Study design
Randomised, active-controlled, parallel group multicentre 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
Thrombocytopenia

Interventions
All patients will be randomised to receive one of three platelet products during one transfusion period:
Arm A: plasma stored platelet concentrates (Plasma-PC)
Arm B: PAS III stored platelet concentrates (PAS III-PC)
Arm C: pathogen reduced PAS III stored platelet concentrates (PR-PAS III-PC)

Duration of study will be one transfusion period, which is defined as a period of six weeks or a maximum of five transfusions.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
One-hour CCI.

Secondary outcome measures
1. 24 hour CCI
2. Bleeding grade minimal two (Common Terminology Criteria for Adverse Events version three [CTCAE v 3.0])
3. Transfusion requirement, red cells and platelets
4. Platelet transfusion interval
5. Adverse transfusion reactions

Overall study start date
01/02/2007

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Age minimal 18 years
2. Expected minimal two platelet transfusion requirements
3. Written informed consent
4. Having a haemato-oncological disease

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
300

Key exclusion criteria
1. Known immunological refractoriness to platelet transfusions, i.e. human leukocyte antigen (HLA)- and/or human platelet antigen (HPA)-alloimmunisation and/or clinical relevant auto-antibodies
2. Pregnancy (or lactating)
3. Previous inclusion in this study

Date of first enrolment
01/02/2007

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
HagaHospital
Den Haag
Netherlands
2545 CH

Sponsor information

Organisation
Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (The Netherlands)

Sponsor details

HOVON Data Center
Erasmus Medical Centre
Daniel den Hoed Clinic
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Sponsor type
Research organisation

Website
http://www.hovon.nl/

ROR
https://ror.org/056kpdx27

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Haemato-Oncology Association (Stichting Hemato-Oncologie Volwassenen Nederland) (HOVON) (The Netherlands)

Funder Name
The Sanquin Blood Supply Foundation (Stichting Sanquin Bloedvoorziening) (The Netherlands)

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