Markers of endothelial activation and damage in haematological patients in relation to efficacy of transfusion support: a pilot study.

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The determination of a panel of markers associated with endothelial cell activation and/or damage in patients with a hematologic malignancy, receiving intensive treatment, or sickle cell disease in relation to the effects of transfusion intervention...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON31260

Source
ToetsingOnline

Brief title
The marker study

Condition

- Haematological disorders NEC

Synonym
blood diseases, Haematological diseases

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: Stichting Sanquin Bloedvoorziening

Intervention

Keyword: Endothelial cells, Hematological patients, Markers, Transfusions

Outcome measures

Primary outcome

Clinical endpoints:

For the hemato-oncological patients:

- bleeding complications

- transfusion efficacy

For the SCD patients

- occurence/existence of organ damage

Laboratory determination of:

P-selectin, activated leukocytes, micro-particles, integrines and cytokines by

flowcytometry;

Hyaluronic acid, vWF and its propeptide with ELISA technique;

and platelet aggregation assays.

Gene expression.

Secondary outcome

not applicable

Study description

Background summary

Supportive care with platelet and red blood cell transfusions is standard practice in both malign as benign haematological diseases. Despite the large scale usage of bloodproducts there are still a large number of unresolved issues with regard to indications and efficacy. There is concrete evidence in literature that patient-related pathophysiologic processes are the main determinants of transfusion outcomes and clinical complications. Evidence suggests an important role of endothelial cell activation and damage, and a number os studies indeed has shown correlations between different markers of endothelial damage and clinical complications. This pilot study aims to test a number of markers of endothelial activation and damage in relation to clinical outcome and transfusion efficacy. The goal, eventually, is to identify markers useful to test in clinical transfusion studies.

Study objective

The determination of a panel of markers associated with endothelial cell activation and/or damage in patients with a hematologic malignancy, receiving intensive treatment, or sickle cell disease in relation to the effects of transfusion intervention.

Study design

In 20 patients with a hemato-oncological malignancy, receiving intensive treatment, blood samples will be drawn before en after platelet transfusion. In patients with SCD treated with chronic exchange transfusions blood samples will be drawn before and after the exchange. In SCD patients not treated with transfusions a single blood sample will be drawn.

Inclusion criteria: informed consent, age > 18 years, hemato-oncological disease or Sickle cell disease.
Exclusion criteria: active cardiovascular disease, recent thromboembolism.

Some laboratory tests will be performed immediately, however for logistical reasons a part of the samples will be stored for later determination.

Clinical outcomes will be acquired using the medical charts and administrated in case report forms.

After completion of the pilot study, the patient characteristsics as well as clinical outcome will be analysed using chi-square tests. The laboratory values will be compared using a student-t test.

Study burden and risks

There are no additional risks associated with participation and only a minor burden (venous blood sampling).

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

1. Age > or <= 18 years
2. Hemato-oncologic diagnosis, expected to receive > 2 platelet transfusions
3. patients with sickle cell disease
4. informed consent

Exclusion criteria

1. Active cardiovascular disease
2. Recent thrombotic event
3. The usage of Ascal

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2007
Application type:	First submission
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
CCMO	NL16512.098.07