Platelet activity test study

Published: 16-08-2010
Last updated: 04-05-2024

In the platelet activity test study (PATS) we aim to perform a pilot to validate the platelet activity test for use in our laboratory and test the logistics of sample processing, in the setting of the BOP study, before starting the clinical trial in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational non invasive

Summary

ID

NL-OMON36813

Source
ToetsingOnline

Brief title
PATS

Condition

- Leukaemias

Synonym
bleeding

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Sanquin

Intervention

Keyword: activity, hematology, oncology, platelet

Outcome measures

Primary outcome

Platelet activity measurements.

(feasibility of logistics and standardized test)

Secondary outcome

Correlation with bleeding symptoms.

Study description

Background summary

In preparation of a large clinical trial, that will evaluate the effectiveness of different platelet products against bleeding and the prediction of bleeding in hemato-oncology patients, an observational pilot study of bleeding episodes in these patients has recently been approved (the BOP study, protocol number:). A flowcytometric platelet activity test has previously been developed in the University Medical Center Utrecht. During the clinical trial the predictive value of this platelet activity test will be determined, for the prediction of bleeding.

Study objective

In the platelet activity test study (PATS) we aim to perform a pilot to validate the platelet activity test for use in our laboratory and test the logistics of sample processing, in the setting of the BOP study, before starting the clinical trial in which we will develop our prediction models.

Study design

During vena-puncture for routine care (daily platelet counts, and platelet counts for monitoring of transfusion success) one additional tube of blood will be drawn (4.5 mL, into citrate). Additionally, before platelet transfusion, a small sample will be taken from the platelet product to be transfused. These samples will be tested in the flowcytometric platelet activity test and results will be linked to the results from the BOP study.

Study burden and risks

No risks and negligible burden anticipated.
No direct benefits for participants, but benefits for the group of patients could be considerable: prevention of bleeding and unnecessary transfusions in future patients.

Contacts

Public
Sanquin Bloedbank

Plesmanlaan 1a
2333 BZ Leiden
NL
Scientific
Sanquin Bloedbank

Plesmanlaan 1a
2333 BZ Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older.
hemato-oncological disease.
expected to receive two or more platelet transfusions.

Exclusion criteria

TTP,HUS,ITP
anti-coagulant or anti-platelet drug use.
active bleeding.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2010
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-08-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-10-2012

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-06-2013
Application type:	Amendment
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	NL32996.058.10