How does pneumatic tube transportation of thrombocyteconcentrates for transfusion purposes influence the thrombocyte in vivo function?

Published: 12-09-2014
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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Platelet disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55358

Source
ToetsingOnline

Brief title
Thrombocyteconcentrate in vivo function after transportation.

Condition

- Platelet disorders

Synonym
lack of bloodplatelets, thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fibrinolysis, in vivo function, thrombopenia

Outcome measures

Primary outcome

Increment of transfuion after 1 and 24 hours (measured by number of

thrombocytes and corrected ammount increment-CCI)

Differences of

Mean platelet volume (MPV)

Whole blood impedance measurement (activated by ADP/TRAP/COLL/ASPI)

CD62

Microparticles

PFA-100

Thrombelastography (for fibrinolysis)

Secondary outcome

Incidence of spontaneous bleeding irrespective TC transfusion.

Study description

Background summary

Bloodproducts should be of good quality to reach optimal transfusion efficacy. Furthermore bloodproducts are primarily given to acute bleeding patients or to patients at high risk of bleeding. For this reason the process from decision to transfusion should be performed as quick as possible.
In the academic medical center Maastricht there are two pneumatic systems. The one is used for transport of specimens wheras the second is used for transport of bloodproducts (packed cells, FFP, thrombocyte concentrates) for transfusion purpose.

Nevertheless there is concern about potential disadvantages. The reason for this is the high acceleration and deceleration which cause mechanical stress to the cells. As a result there could be thrombocyte dysfunction which will be seen in inadequate transfusion success, formation of unstable clots and even boosted fibrinolysis. Actual research showed no consequences of pneumatic tube transport on thrombocyte concentrates in vitro. But still there are no data on the effects in vivo.

Study objective

Aim of the study is to show the feasibility of pneumatic tube transport of thrombocyte concentrates. The efficacy will be measured by thrombocyte increment (CCI) and thrombocyte funtion analysis. This shall lead to routine transportation of TC*s to the day care center for the purpose of transfusion to our selected population. This shall lead to more patient contentment

Study design

The study will use a Simon*s two stage design. After inclusion of 20 patients, we will perform an interim analysis. If 16 or less patients have a good thrombocyte increment, the study will be stopped. If this is not the case, 38 extra patients will be included (in total 58).

Study burden and risks

There will be only an interview for the informed consent. Furthermore 52.5 ml blood (overall) will be drawn from the central venous line.
Participants will receive coffee or tea and a compensation for traveling of 20 euros.

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

thrombocytopenia (<10 x 109/L) with an indication for prophylactic platelet transfusion
adults
informed consent

Exclusion criteria

Infection and sepsis, active bleeding, splenomegaly
Treatment with anticoagulants (LMWH, acetylic acid, coumarines)
Thrombocyte transfusion shorter than 72 hours ago
Temperature above 37.9 degrees Celsius

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2015
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-02-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-01-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL47681.068.14