Platelet function preservation after intraoperative autologous blood donation in cardiac surgery

Published: 29-01-2008
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To reduce postoperative blood loss by improving platelet function in autologous blood donation

Ethical review	Approved WMO
Status	Pending
Health condition type	Platelet disorders
Study type	Interventional

Summary

ID

NL-OMON31386

Source
ToetsingOnline

Brief title
platelet preservation in cardiac surgery

Condition

- Platelet disorders
- Cardiac therapeutic procedures

Synonym
platelet function

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Afdelinges gelden;reagentia en test buizen door firma (Multiplate)

Intervention

Keyword: cardiac surgery, platelet, preservation

Outcome measures

Primary outcome

for part I, in vitro platelet function during period of cardio pulmonary bypass.

for part II, reduction of blood loss and quality of clotting

(Thromboelastogram and platelet function) after cardio pulmonary bypass.

Secondary outcome

quality and quantity of blood clotting and platelet function after 2 hours in

Intensive Care. Rethroacotomies for increased blood loss

Study description

Background summary

During heart surgery autologous blood donation is used to preserve platelet function. Literature search shows no benefit of storage in either citrate or heparin. Both preservation techniques reduce platelet function over time irreversibly. For this study an alternative strategy is studied to improve platelet preservation.

Study objective

To reduce postoperative blood loss by improving platelet function in autologous blood donation

Study design

The study consists of two parts. In part one the best alternative preservation strategy is choosen with in vitro tests. In part two of the study this strategy is tested for clinical effects on blood loss and tranfusion need against a control group wereby blood is donated in heparin.

Intervention

Comparison of autologous blood transfusion preserved in heparin (control group) against an alternative strategy (blood preserved in bivalirudin).

Study burden and risks

There is no burden for the patietn. The study is carried out during the period under anesthesia. There are no additional risks for the patients. Autologous blood donation is a standard therapeutic procedure in our centre for cardiac surgery.

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

haemoglobin level of 8 mmol/L

Exclusion criteria

use of platelet inhibitors

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	71
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL19196.042.07