The effects of on the rheologic properties and oxygen transport capacity of red blood cells processed by 3 different types of cell savers, and its effects on microcirculatory blood flow and tissue oxygenation in vivo

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON40462

Source
ToetsingOnline

Brief title
Cell savers and blood quality

Condition

- Coronary artery disorders

Synonym
blood quality, cell saver

Research involving

Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cell saver, microcirculatory blood flow, rheologic properties

Outcome measures

Primary outcome

Primary endpoint of this study is the quality of the washed red blood cells,

measured by their deformability and oxygen carrying capacity

Secondary outcome

the effects of retransfusion of washed cell saver blood in the patient measured

by microcirculatory blood flow and tissue oxygenation, and by biochemical

markers of organ damage.

Study description

Background summary

Cell savers are routinely used in our hospital during off-pump coronary artery bypass grafting to retrieve and wash blood that is lost during the operation. This washed blood is retransfused to the patient in order to prevent allogeneic blood transfusion. However, little is known about the rheologic properties and oxygen transport capacity of the washed red blood cells and the effects of retransfusion of this blood on microcirculatory blood flow and organ damage in the patient.
For cell savers 3 different operating principles exist. The most common one uses discontinuous blood washing with a spinning bowl that is intermittently filled with blood, processed and emptied. A second one uses a continuous blood washing principle with a rotational disk. A third one is intermediate using features of both the discontinuous bowl technology and the continuous rotational disc technology.

We hypothesize that the operating principle has effects on the rheologic properties and oxygen transport capacity of the washed blood. Previous research suggested that in particular the deformability and oxygen carrier properties of the red blood cells are affected. As a consequence, red blood cells may block small blood vessels, which affects microcirculatory blood flow and tissue oxygenation. This may lead to organ damage.

Study objective

The objective of this study is to determine in vitro the rheologic and oxygen transport capacity of the washed blood processed by one of 3 different cell savers and to measure in vivo after retransfusion of this processed blood in the patient the effects on microcirculatory blood flow and tissue oxygenation using laser doppler and near infra-red spectroscopy, and on organ damage using organ specific biomarkers.

Study design

Randomized Prospective, interventional trial

Intervention

randomized to one of the three cellsavers

Study burden and risks

The microcirculatory blood flow is measured with a small 3 mm thick sensor in the mouth of the patient. This may be considered as a burden for the patient on the first postoperative day when they are awake. Blood (30 mL in total) for analysis of biomarkers will be drawn from an arterial line that is routinely inserted for these operations. Urine (15 mL in total) will be collected from the urinary catheter that is routinely inserted for these operations. Due to the observational character of this study and the non-invasive microcirculatory measurements, the risks for the patients are negligible. Up to now we are unaware of adverse events related to the use of the cell savers or the microcirculatory measurements. Participation will therefore not increase the risk of the operation, but will also not have immediate benefits for the individual patient.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Scheduled for OPCABG
age>18 year

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
Patients with known hematologic or microvascular disorders. Patients will be excluded intraoperatively when conversion to on-pump coronary artery bypass grafting is necessary or when allogeneic red blood cell transfusion is required

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	10-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-01-2015
Application type:	Amendment
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	NL42913.042.13