Redon drain blood quality before and after cell saver processing during CABG procedures: a pilot study

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• To measure the quality of the red blood cells of redon drain blood before and after cell saver processing.• To measure the effects on whole redon drain blood in terms of inflammatory activation, platelet activation and blood rheology in the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON49048

Source
ToetsingOnline

Brief title
Redon drain cell saver

Condition

- Coronary artery disorders

Synonym
autotransfusion, transfusion with own blood

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bypass surgery, cell saver

Outcome measures

Primary outcome

Blood rheology

Secondary outcome

Blood gas parameters

Baseline platelet activation and activation triggered by a receptor activator

Inflammatory markers: Interleukin -6 (CXCL6), Interleukin -8 (CXCL8) and tumor

necrosis factor-α (TNF-α)

Hemolysis index

Study description

Background summary

In order to minimize the need for allogenic blood transfusion it is desirable to auto-transfuse as much of the patients own blood as possible. In coronary artery bypass grafting (CABG) the saphenous vein from the leg is routinely used as graft material. It is currently unknown to what extend the immune- and coagulation systems are activated and adequate blood rheology is maintained in redon drain blood over time. It is also unclear to what extend this affects the quality of the red bloods cells after cell saver processing. Therefore the aim of this research is to measure the activation of the immune- and coagulation system as well as determining the rheological properties of the RBCs in the redon drain during the surgery and after cell saver processing.

Study objective

• To measure the quality of the red blood cells of redon drain blood before and after cell saver processing.

• To measure the effects on whole redon drain blood in terms of inflammatory activation, platelet activation and blood rheology in the patient before and

after the surgical procedure and in the redon drain before and after cell saver processingat various time points intraoperatively.

Study design

The study will be a prospective repeated measures pilot study in the UMCG.

Study burden and risks

There is no strain on the participating patient during the research. The patient is under anesthesia and only a very small blood sample of 10 ml in total is collected. There will be no changes to the standard care for the participants. All blood collection and processing will be carried out by well trained personnel that is used to working in the OR environment. Therefore there is no foreseeable risk involved with participation in this study.

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

Scheduled for elective CABG with the use of saphenous vein graft material
Age >=18 years
Capable of understanding and speaking Dutch.

Exclusion criteria

Hematologic disorders
Sepsis
Unable to correctly understand the research by means of different langue barrier or mental impairment
Less than 50 ml of blood has been collected in the redon drain at the end of the surgery

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	12-02-2020
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	NL71988.042.19