In vivo study of pulse conductance of oxygenators during pulsatile flow

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20861

Source
NTR

Brief title
Pulse Conductance of Oxygenators

Health condition

oxgenator
pulsatile flow
heart-lung machine

Sponsors and support

Primary sponsor: Jos G. Maessen, MD PhD
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Intervention

Outcome measures

Primary outcome

To measure pulse conductance of two standard types of oxygenators standard used during coronary artery bypass surgery using a standard heart-lung machine.

Secondary outcome

To measure/record the standard normalized index of haemolysis during elective coronary artery bypass surgery using a standard heart-lung machine.

Study description

Background summary

Rationale: The objective of this clinical study is to endorse the hypothesis that oxygenators with a relatively high compliance and relatively low hydraulic resistance enable better pulse conductance than relatively stiff oxygenators featuring relatively high resistance.

Objective: Primary objective: measure pulse conductance of two standard types of oxygenators standard used during coronary artery bypass surgery using a standard heart-lung machine.

Secondary objective: measure/record the standard normalized index of haemolysis during elective coronary artery bypass surgery using a standard heart-lung machine.

Study design: prospective controlled randomized observational study

Study population: 40 patients undergoing elective coronary artery bypass grafting (CABG) using extracorporeal circulation.

Intervention (if applicable): no intervention, standard CABG procedure only

Main study parameters/endpoints: Pulse conductance of the oxygenator used during pulsatile perfusion with a standard heart-lung machine, and the normalized index of haemolysis measured in relation to the oxygenator used during pulsatile perfusion with a standard heart-lung machine.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No other or additional risk than for those patients that do not involve in the study, and that undergo coronary artery bypass surgery. Differences in the two groups of standard oxygenators regarding primary and secondary objective is to be investigated. Both devices, however, have been clinically used for more than 15 years, and have been established as equivalent devices to take over lung function during heart surgery using extracorporeal circulation.

Regarding the results of the in vitro investigation in which the Quadrox had a better pulse conductance than the Capiox SX18, we expect a better pulse conductance in the Quadrox group in the clinical study as well. This would imply a less aggressive pulse generation in the Quadrox group, thus a reduced haemolysis. In standard clinical (non investigational) treatment, however, over the last 15 years, the haemolysis when using the Capiox SX18 oxygenator has not stood out. Therefore, we do not expect any complications in this group.

Study objective

The objective of this clinical study is to endorse the hypothesis that oxygenators with a relatively high compliance and relatively low hydraulic resistance enable better pulse conductance than relatively stiff oxygenators featuring relatively high resistance.

Study design

Baseline measurement of free hemoglobin before initiation of cardiopulmonary bypass and after 30 min on cardiopulmonary bypass; continuous recording of line pressures after initiation of cardiopulmonary bypass.

Intervention

Non-interventional study, therefore non-applicable

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients scheduled for elective CABG using a standard heart-lung machine with either a standard used Maquet Quadrox HMO 2000 oxygenator, or a standard clinically equivalent Terumo Capiox SX18 oxygenator, using standard pulsatile perfusion at the university hospital Maastricht.

2. Calculated bypass flow of 5 l/min.

3. Written informed consent.

4. Age of 18 and older.

Exclusion criteria

1. All other patients that do not comply with the inclusion criteria given above, e.g. patients receiving valve surgery, or combined CABG / valve surgery.

2. No written informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-06-2008
Application type:	First submission

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
NTR-new	NL1298
NTR-old	NTR1346
Other	ABR NL22896.068.08 : MEC 08-2-036
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results