In vivo study of pulse conductance of oxygenators during pulsatile flow

Published: 04-06-2008
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32106

Source
ToetsingOnline

Brief title
Pulse conductance of oxygenators

Condition

- Coronary artery disorders

Synonym
coronary surgery, open-heart surgery

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: heart-lung machine, oxgenator, pulsatile flow

Outcome measures

Primary outcome

Puls conductance of the oxygenators Maquet Quadrox HMO 2000 and Terumo Capiox SX18 during pulsatile perfusion with a heart-lung machine.

Secondary outcome

Blood damage, measured on the basis of standard measured/determined normalized index of hemolysis during pulsatile perfusion with a heart-lung machine.

Study description

Background summary

During CABG heart surgery the patient's heart is stopped from beating. During this heart arrest, the body circulation of the patient is maintained using a heart-lung machine for perfusion. In the university hospital Maastricht standard uses a pulsatile heart-lung machine, in other words, an artificial pulsating blood flow. Before the generated pulsatile blood flow is pumped to the patient, the blood flow (pulse) flows through an artificial lung, the so called oxygenator. Because of its mechanical properties (elasticity and resistance) the oxygenator affects the pulse; the oxygenator dampens and reduces the pulse.

That the oxygenator affects the pulsatile blood flow is a common known fact to every clinician, but data (publications) in which the effect of the oxygenator on the flow pulse is quantified has, as far as we know, not been published. Also, the influence of the oxygenator during pulsatile perfusion on blood damage has, as far as we know, not been studied yet.

Study objective

This study examines the pulse conductance of two oxygenators, that have been used in the clinic for more than 15 years now, and are regarded as clinically equivalent. For this study, it is sufficient to evaluate and compare postoperatively standard recorded per-opative perfusion data . In addition, we

will be able to confirm previously found in vitro data on pulse conductance of oxygenators. Moreover, next to these aspects, the standard recorded perfusion data can be used to compare the two oxygenators on blood damage. This blood damage can be determined using standard taken per-operativel blood samples.

Study design

Prospective controlled randomized observational study.

Study burden and risks

No additional risks compared to those with the standard procedure of CABG 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

-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.
-Written informed consent.

Exclusion criteria

-All other patients that do not comply with the inclusion criteria given above, e.g. patients receiving valve surgery, or combined CABG and valve surgery.
-No written informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2008
Application type:	First submission

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	NL22896.068.08
Other	www.trialregister.nl, nummer nog onbekend