Haemolysis during extracorporeal CO2 removal; an in vitro study using donated human blood

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This in vitro study aims at investigating a possible relationship between plasma free haemoglobin, catheter diameter (i.e. resistance), pump rotational speed, pump heating and pump flow using freshly donated human blood in a mock circulation of an...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON41022

Source
ToetsingOnline

Brief title
In vitro haemolysis using human blood

Condition

- Other condition

Synonym
n.v.t., zie C21

Health condition

Het betreft geen directe aandoening. Het betreft een in vitro onderzoek gebruik makend van donorbloed. De donoren zijn gezonde vrijwilligers.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: blood, CO2 removal, haemolysis, in vitro

Outcome measures

Primary outcome

in vitro plasma free haemoglobin

Secondary outcome

-in vitro circuit temperature

-in vitro circuit blood flow rate

-in vitro circuit pressure

Study description

Background summary

Extracorporeal life support (ELS) has proven a successful technique to provide cardiopulmonary assistance in acute heart and/or lung failure using supporting blood flows of 3-6 l/min. Adapted towards a low-flow application using supporting blood flows of approximately 0.5-1.0 l/min and small catheters, ELS can be used for extracorporeal CO2 removal in patients suffering from exacerbation of chronic obstructive pulmonary disease.

The use of relatively small catheters, however, opposes a challenge for the blood pump. Small bore catheters induce an increased blood flow resistance. To compensate for such hydraulic resistance, pump speeds must be increased. Increasing pump speed while pump flow remains relatively low, however, can lead to pump heating. Such pump heating as well as high pump rotational speeds may cause haemolysis. Haemolysis with resultant increased levels of plasma free haemoglobin leads to kidney damage, which in patients undergoing cardiac surgery has shown to affect clinical outcome.

Study objective

This in vitro study aims at investigating a possible relationship between plasma free haemoglobin, catheter diameter (i.e. resistance), pump rotational speed, pump heating and pump flow using freshly donated human blood in a mock circulation of an extracorporeal life support for CO2 removal.

Study design

In this prospective study an in vitro setup will be filled with donated fresh human blood from healthy volunteers willing to donate approximately 200 ml. Blood will be drawn by a physician and collected in a blood donation bag containing citrate for anticoagulation.

Intervention

vena punction and whole blood donation

Study burden and risks

There are no direct benefits for the healthy volunteers willing do donate whole blood. Blood is drawn by a vena punction by an experienced physician. Blood is donated under standard transfusion laboratory conditions, i.e. lying on a bed, with vital parameter monitoring, and fluid supply during and after donation. Moreover, since the donated volume (approximately 200 ml) amounts to approximately 4% of the human blood volume (5 litres), no hemodynamic consequences are to be expected. Standard risks are pain, fainting and infection.

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

healthy volunteer

Exclusion criteria

-volunteers known with anaemia or those not feeling well
-volunteer that has taken part in this study or donated blood during the past 7 days

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2014
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	10-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-01-2015
Application type:	Amendment
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	NL49743.068.14

Study results

Date completed:	23-01-2015
Actual enrolment:	33