Haemolysis during extracorporeal CO2 removal; a laboratory study using donated human blood.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25081

Source
NTR

Health condition

Haemolysis, extracorporeal CO2 removal, low flow CO2 removal, extracorporeal life support, ELS, COPD, exacerbation, chronic obstructive pulmonary disease, acute lung failure.

Hemolyse, extracorporale CO2 verwijdering, extracorporale ondersteuning, exacerbatie, acuut longfalen.

Sponsors and support

Primary sponsor: University Medical Centre
Source(s) of monetary or material Support: University Medical Centre

Intervention

Outcome measures

Primary outcome

Normalised index of haemolysis (NIH).*

*Plasma free haemoglobin is measured in duplo at the beginning and end of an in vitro run in order to calculate the NIH.

Secondary outcome

Pump speed (in rpm).

In vitro circuit pressures (in mmHg).

In vitro circuit temperature (in oC).

Study description

Background summary

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

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. Different catheter sizes and flow rates are used (in triplo) in order to investigate a relationship between haemolysis (plasma free haemoglobin) and extracorporeal life support-related parameters such as pump flow, catheter selection, pump speed, pump pressures and pump heating.

Study objective

Objective: to investigate in vitro a relationship between plasma free haemoglobin and extracorporeal life support-related parameters such as pump flow, catheter selection, pump speed and pump heating.

1. Blood flow is positively related to plasma free hemoglobin, circuit pressures and circuit temperature.

2. Decreasing catheter diameter aggravates the relationship between blood flow, plasma free hemoglobin, circuit pressures and circuit temperature.

Study design

After choosing a catheter size and flow rate, there are two main timepoints for recording

data:

- 5 minutes after the start of the blood pump: pump speed (pump display), flow rate (pump display), pump inlet / outlet pressures (pump display), circuit temperature before and after pump (temperature probes), free haemoglobin (blood sample in duplo, laboratory maesurement).

- 6 hours after the start of the blood pump: pump speed (pump display), flow rate (pump display), pump inlet / outlet pressures (pump display), circuit temperature before and after pump (temperature probes), free haemoglobin (blood sample in duplo, laboratory maesurement).

Interim recordings (every hour) include blood flow rate, pump speed, temperature and circuit pressures.

Intervention

30 healthy volunteers will donate approximately 200 ml whole blood, drawn by aseptic vena punction by an experienced physician and collected in a blood donation bag containing citrate for anticoagulation. Blood is donated under standard transfusion laboratory conditions, i.e. lying on a bed, with vital parameter monitoring, and fluid supply by drinking water during and after donation.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteer.

Age and gender not relevant.

Exclusion criteria

Volunteers known with anaemia or those not feeling well.

Volunteer that has taken part in this study and has donated blood during the past 7 days.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	30-10-2014
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	NL4746
NTR-old	NTR4874
Other	METC : 142042

Study results