Liver resection and non-invasive measurement of hemoglobin concentration with pulse co-oximetry

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Primary Objective: to evaluate the accuracy of continuous SpHb measurement during hepatic resection compared with standard (invasive) Hb measurementSecondary Objective(s): the effect of a bolus of crystalloid on SpHb level will be compared to the...

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

Summary

ID

NL-OMON33402

Source
ToetsingOnline

Brief title
non-invasive measurement of Hemoglobin concentration with Pulse Co-oximetry

Condition

- Other condition

Synonym
hemoglobine measurement

Health condition

levertransplantatie patienten

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: Hemoglobin concentration, liver resection, non-invasive measurement, Pulse Co-oximetry

Outcome measures

Primary outcome

SpHb level

The blood hemoglobin level measured with the spectrophotometric sensor and from

blood samples taken form the patient and measured of the central laboratory

with an Sysmex XE-2100 analyzer.

Secondary outcome

Effect of a bolus of crystalloid (NaCl 0.9%) on SpHb level will be compared to

the effect of a bolus of colloid (Venofundin) on the SpHb level.

Study description

Background summary

Frequent measuring of the blood haemoglobin (Hb) during hepatic resection is a standard but crucial procedure. This kind of operation is often associated with high intraoperative blood loss. A consequent low blood haemoglobin level is associated with increased cardiovascular events and death.
After the resection is completed patients receive a fluid bolus to normalize their filling status.
The difference of crystalloids and colloid infusion is that crystalloid solutions spread rapidly over the intravascular and interstitial space due to lack of colloid oncotic pressure (COP). The difference in the COP of these to fluids and hence their distribution over the intra- and extra vascular space could be reflected in the measured Hb concentration. (6)(7)
During this procedure frequent measurement of the blood haemoglobin is

important, as a guide for the administration of RBC and as a substitute to monitor blood loss.
Standard procedure to measure the Hb form is to take a blood sample. A disadvantage of this procedure is that every time a sample of 10ml blood must be taken and its takes approximately 10 minutes before the Hb is known.
New advances in pulse oximetry technology have led to the development of multiwavelength pulse CO-oximeters designed to measure multiple physiologic parameters. The utilization of multiple wavelengths has led to the development of a pulse CO-oximeter that allows for measurement of continuous haemoglobin concentration (SpHb). With this method no blood samples are needed and it allows early detection and treatment of potentially life threatening conditions.

Study objective

Primary Objective: to evaluate the accuracy of continuous SpHb measurement during hepatic resection compared with standard (invasive) Hb measurement
Secondary Objective(s): the effect of a bolus of crystalloid on SpHb level will be compared to the effect of a bolus of colloid on the SpHb level.

Study design

pilot study

Study burden and risks

no risks

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

All patients: Age > 18 years
Study group: ASA class I and II patient requiring hepatic resection

Exclusion criteria

Patient refusal
Patients with a perioperative blood loss exceeding 5ml/kg

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

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	NL28548.042.09