Monitoring of intraoperative blood loss: benefit of continuous noninvasive haemoglobin monitoring?

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

Summary

ID

NL-OMON40097

Source
ToetsingOnline

Brief title
Intraoperative monitoring of blood loss

Condition

- Other condition

Synonym
blood loss, haemoglobin monitoring

Health condition

risico op bloedverlies tijdens en na de operatie

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W,masimo met een unrestricted grant

Intervention

Keyword: haemoglobin, intraoperative blood loss, noninvasive

Outcome measures

Primary outcome

The primary endpoint of this pilot study is the total time a patient*s Hb is

below a predetermined transfusion threshold (HbAUC) for administration of red

blood cell concentrate.

Secondary outcome

Secondary endpoints are the number of perioperative blood transfusions,

incidence of overtransfusion, DO2, StO2 and serum concentrations of lactate and

high-sensitive troponin T.

Study description

Background summary

Certain types of surgery are associated with occult blood loss, which is hard to detect intraoperatively by intermittent conventional, invasive Hb concentration measurements using the clinical standard of Hb monitoring by satellite-laboratory analysis (Hbsatlab). We want to see whether continuous non-invasive transcutaneous Hb measurement using a finger sensor (SpHb), (a) reduces the total time (area under the curve, AUC) a patient*s Hb is below a predetermined transfusion threshold (HbAUC) for administration of red blood cell concentrate (RBC), and (b) prevents a decrease in total oxygen delivery (DO2) possibly associated with transfusion below a critical haemoglobin concentration. Furthermore, we want to study if SpHb monitoring changes the timing of RBC administration and reduces the need for intra- and post-operative

RBC transfusion

Study objective

The primary endpoint of this pilot study is the total time a patient*s Hb is below a predetermined transfusion threshold (HbAUC) for administration of red blood cell concentrate. Secondary endpoints are the number of perioperative blood transfusions, incidence of overtransfusion, DO2, StO2 and serum concentrations of lactate and high-sensitive troponin T.

Study design

Randomised controlled pilot study.

Study burden and risks

ince SpHb, StO2 and DO2 measurements are noninvasive and limited to the intraoperative period, there are no additional risks or burden to the patient. High-sensitive troponin T will be measured in both groups at the end of surgery as well as every morning during the first three postoperative days, requiring drawing of 5 ml blood into a standard syringe each time. The postoperative samples will be obtained during the routine laboratory tests. The follow-up data recordings will be taken from standard patient files or the hospital information system; there is no further contact with the patient necessary. In the SpHb group, there is no additional risk as compared to the Hbsatlab group receiving standard therapy: RBC administration is now initiated and guided by continuous SpHb monitoring, possibly changing the timing of its administration.

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 at the age of 18 years or older, planned for elective surgery at-risk for undetected blood loss
-American Society of Anesthesiologists (ASA) classification I, II, III, IV

Exclusion criteria

Patient refusal
- Emergency surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-11-2013
Application type:	Amendment
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	NL42672.042.12