Intraoperative Monitoring and Optimisation of Tissue Oxygenation In High-Risk Surgical Patients for reduction of postoperative complications

Published: 21-12-2010
Last updated: 03-05-2024

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

Summary

ID

NL-OMON34101

Source
ToetsingOnline

Brief title
Intraoperative Optimisation of Tissue Oxygenation

Condition

- Other condition

Synonym
high risk surgery high risk patient

Health condition

hoog risico patienten en/of hoog risico chirurgie

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,hutchinson

Intervention

Keyword: high risk patient, higk risk surgery, postoperative complications, tissue oxygenation

Outcome measures

Primary outcome

The primary end point of the feasibility study will be a to evaluate the

incidence of perioperative complications (organ dysfunction, SOFA score,

troponin T, creatinin, CRP).

Secondary outcome

The secondary end points include feasibility of the interventions.

Study description

Background summary

Tissue hypoxia is supposed to occur frequently during high-risk surgery or in high-risk patients undergoing surgery. However, it is difficult to detect since conventional monitoring devices look either at the input site of the tissues (arterial blood) or at the downstream side of the tissues (venous blood, lactate). Recently, monitoring devices looking into the tissues have been introduced and shown its ability to differentiate between survivors and nonsurvivors (1). Nevertheless, due to a lack of available methods there is a very limited use of monitoring tissue oxygenation intraoperatively (i.e. in the OR) as of yet.
Undetected intraoperative tissue hypoxia may contribute to postoperative organ dysfunction, prolonged ICU or hospital stay, and increased mortality. Furthermore, there is a lack of protocols for the perioperative management of high-risk surgical (HRS) patients. Recently, there is evidence that the use of a goal directed therapy might improve survival (2) and reduce the incidence of

postoperative complications (3-5).
The purpose of this clinical study is to obtain human clinical data in order to demonstrate that a decrease in the incidence of post-operative complications can be achieved by following an optimizing protocol, based on targeting tissue oxygenation (StO2).
Tissue oxygenation (StO2) will be monitored by near infrared spectroscopy, a non-invasive technique. It has been shown to be of value in predicting organ dysfunction in trauma patients (6) as well as outcome in patients with sepsis (1, 7). Also in the perioperative setting it has been demonstrated recently that low StO2 is associated with worse outcome (8).
We hypothesize that monitoring and treating tissue hypoxia (defined as a StO2<80%) with the use of a protocol will reduce postoperative complications in high-risk surgical patients.

Study objective

Tissue hypoxia occurs frequently during high-risk surgery in high-risk patients. We want to see if an algorithm aimed at optimizing intraoperative tissue oxygenation reduces perioperative complications as well as length of stay in the intensive care unit (ICU LOS), 28-day mortality, and the duration of mechanical ventilation in these patients

Study design

randomized pilot study

Intervention

If despite volume expansion the StO2 will be below 80%, norepinephrine (initial dose 0.03 ug/kg/min) and/or dobutamine infusion (initial dose of 2.5 ug/kg/min) will be started and gradually increased until the goal is reached. In addition, packed red blood cells will be given if needed. These interventions all belong to standard care, only its timing will be guided by the StO2 readings according to a fixed protocol.

Study burden and risks

Since the intervention is limited to the intraoperative phase, there will be no additional burden for the patient. The follow-up data recordings will be taken from standard patient files or hospital information system; there is no contact with the patient necessary. In the intervention group, there is no additional risk as compared to the control group receiving standard therapy, unless start of fluid or vasoactive therapy is now initiated and guided by the monitoring of StO2.

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

•Major elective surgery
•Aged over 65 years with moderate functional limitation of one or more organ systems
•ASA classification III or IV, i.e. severe cardiac, vascular, respiratory or metabolic illness resulting in severe functional limitation
•Routine use of arterial and central venous lines
•Planned postoperative stay on ICU or PACU

Exclusion criteria

• Refusal of consent
• acute myocardial ischemia prior to enrolment

• patients receiving palliative treatment only
• disseminated malignancy
• patients unlikely to survive more than 6 hours
• emergency surgery
• transplantations
• neurosurgical patients
• patients undergoing extensive liver surgery requiring low CVP management

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	InSpectra® System CE 0086
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-12-2010
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	NL33081.042.10