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A comparison between cardiac output monitoring using (minimally invasive) esophageal Doppler and (noninvasive) thoracic electrical bioimpedance

Submission date
20/09/2017

Recruitment status
No longer recruiting

Registration date
02/10/2017

Overall study status
Completed

Last Edited
25/09/2017

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During major abdominal surgery patients need to be monitored carefully to ensure that tissues have an adequate blood supply (perfusion) and level of oxygen (oxygenation). This requires monitoring of cardiac (heart) output and stroke volume (the volume of blood per beat) to determine the use of fluids and medication to improve blood pressure and flow. During operations the ideal monitor of cardiac output is as minimally invasive as possible. The aim of this study is to investigate a monitor that is non-invasive and compare it to a widely used minimal invasive monitor. The minimal invasive monitor (esophageal Doppler probe) requires an oral or nasal placed catheter (tube), and the non-invasive device (Aesculon) requires only four electrodes placed in the neck and thorax of the patient.

Who can participate?
Patients aged over 18 who are scheduled for elective major abdominal surgery

What does the study involve?
Under anaesthetic, the esophageal Doppler probe and the Aesculon device are placed on the participant. Cardiac output measurements are performed at eight time points: directly after the start of anaesthesia, after skin incision (cutting), during the surgical procedure when the patient is in a stable condition, after skin closure, just before extubation (removal of breathing tube), and 30 and 60 minutes after arrival in the recovery ward.

What are the possible benefits and risks of participating?
There is no interference with standard care and monitoring. The only difference to standard care is the placement of four additional electrodes.

Where is the study run from?
Maastricht University Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
January 2009 to January 2010

Who is funding the study?
Maastricht University Medical Centre (Netherlands)

Who is the main contact?
Mr Boris Cox

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC 09-4-052

Study information

Scientific Title
Accuracy, precision and trending ability of electrical cardiometry cardiac output versus esophageal Doppler: a prospective, observational study

Study objectives
The aim of this study is to compare the accuracy, precision and trending ability of cardiac output measurements of a thoracic bioimpedance technique with esophageal Doppler, before, during and after major abdominal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Maastricht University Medical Center, 20/07/2009, ref: MEC 09-4-052.2

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Measurement of cardiac output with different devices in patients sheduled for major abdominal surgery

Interventions
Participants are randomly sampled from patients undergoing major abdominal surgery. They receive the standard level of care during surgery. After induction of anesthesia, a esophageal Doppler probe and the Aesculon device are placed on the participant. The index test is a thoracic electrical bioimpedance cardiac output monitor (Aesculon, Osypka Medical, Berlin, Germany). The reference test was a esophageal Doppler probe (CardioQTM, Deltex Medical, Chichester, United Kingdom), using the I2C 72-probe for nasal introduction.

The only difference to standard care was the placement of four additional electrocardiography electrodes. Two electrodes are placed in the neck and two are placed at the thoracic level. Only data from standard monitoring and bioimpedance were recorded. All measurements are performed at certain time points and there was no interference with standard care and monitoring. There was no need for follow up within this study group. Measurements are performed at eight time points: (T1) directly after induction of anesthesia, (T2) after skin incision, during the surgical procedure when the patient was in a stable condition (T3, T4) were performed at a random moment, (T5) after skin closure, (T6) just before extubation, (T7) 30 minutes and (T8) 60 minutes after arrival on the recovery ward.

Intervention Type
Device

Primary outcome measure
1. Accuracy and precision is measured using Bland Altman analysis by comparing results from the esophageal Doppler to the results of the bioimpedance cardiac output monitor at the eight timepoints. The esophageal Doppler is validated against pulmonary artery catheter, the more or less gold standard of cardiac output measurement. So, the Doppler technique represents the gold standard in this study
2. Trending ability of the techniques is evaluated applying four-quadrant plot and polar plot methodology

Secondary outcome measures
Errors in bioimpedance measures are assessed using interruption of the skin's integrity and opening of the abdominal cavity by a surgical incision at the time of surgery

Overall study start date
10/01/2009

Completion date
07/01/2010

Eligibility

Key inclusion criteria
1. Patients scheduled for elective major abdominal surgery
2. > 18 years old
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 participants

Key exclusion criteria
1. Nasal, pharyngeal, laryngeal or esophageal pathologies
2. Beeding disorders
3. Cardiac arrhythmias
4. Age < 18 years
5. No informed consent

Date of first enrolment
25/08/2009

Date of final enrolment
06/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Maastricht University Medical Centre
Department of Anesthesiology and Pain Management
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Sponsor information

Organisation
Maastricht Universitair Medisch Centrum

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Sponsor type
Hospital/treatment centre

Website
http://www.mumc.nl

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maastricht Universitair Medisch Centrum

Results and Publications

Publication and dissemination plan
Submission of the paper is scheduled for October 2017 and publication for February/March 2018. Additional documents are available on request.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from P.B.W. Cox.

IPD sharing plan summary
Available on request