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A comparison between cardiac output monitoring using (invasive) pulmonary artery catheter and (noninvasive) thoracic electrical bioimpedance

Submission date
24/05/2017

Recruitment status
No longer recruiting

Registration date
01/06/2017

Overall study status
Completed

Last Edited
28/03/2018

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During cardiac surgery, patients are monitored to evaluate cardiac function. In patients scheduled for cardiac surgery this usually includes either the use of a pulmonary arterie thermodilution catheter (PAC) or endotracheal echocardiography. At the time the study was conducted PAC was the golden standard. Newer devices have come out that need research in order to ensure that they are accurate and precise at measuring cardiac output. The aim of this study is to compare the AesculonTM bioimpedance electrical cardiometry (Aesc) to the pulmonary artery thermodilution catheter (PAC) technique before, during and after cardiac surgery.

Who can participate?
Adults aged 18 and older who are scheduled for cardiac surgery.

What does the study involve?
Participants who are undergoing cardiac surgery are randomly selected to participate in this study. After induction of anaesthesia, a PAC and the AesculonTM device are placed on the participant. Participants are measured using the standard pulmonary artery catheter and a thoracic electrical bioimpedance monitor. They have four additional electrodes placed on their neck and chest. Data from the monitors are recorded at certain time points to measure the accuracy and precision of the PAC compared to the Aesc.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

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?
November 2008 to November 2010

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

Who is the main contact?
Mr Boris Cox
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC 08-4-075

Study information

Scientific Title
Accuracy, precision and trending ability of electrical cardiometry cardiac output versus pulmonary artery thermodilution method: a prospective study

Study objectives

The aim of this study is to compare the accuracy, precision and trending ability of a thoracic bioimpedance technique with pulmonary artery thermodilution before, during and after surgical intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Maastricht University Medical Center, 15/12/2008, ref: MEC 08-4-075

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
No participant information sheet available

Health condition(s) or problem(s) studied
Measurement of cardiac output with different devices in patients scheduled for cardiac surgery.

Interventions
After obtaining written informed consent of each patient, participants are randomly sampled from patients undergoing cardiac surgery. They receive the standard level of care during surgery. After induction of anesthesia, a pulmonary artery catheter (PAC) and the AesculonTM 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 pulmonary artery catheter (Edwards Life sciences Corporation, Irvine, CA, USA, Continuous Cardiac Output VIP catheter with SvO2, model 746F8).

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. There were no benefits or risk for patients taking part in this observational study.

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 six time points: after induction and prior to incision (T1), prior to cannulation of the aorta (T2), ten minutes after protamine administration (T3), 30 minutes

after arrival in the ICU (T4), 1 hour after extubation (T5), and one day post-operatively at 08.00 AM (T6).

Intervention Type
Device

Primary outcome measure
1. Accuracy and precision are measured using Bland Altman analysis by comparing results from the clinical gold standard pulmonary artery catheter to the results from the new device, the bioimpedance cardiac output monitor at 6 time points, after induction and prior to incision, prior to cannulation of the aorta, ten minutes after protamine administration, 30 minutes after arrival in the ICU, one hour after extubation, and one day post-operatively.
2. Polar plot methodology was used to objectify trending ability of the new technique (AesculonTM).

Secondary outcome measures
Our secondary aim was to assess whether the surgical incision, and therefore the interruption of the continuity of the skin of the thoracic cavity and opening of the cavity itself, could be an important factor in the reported discrepancy between the two instruments.

Overall study start date
01/11/2008

Completion date
12/11/2010

Eligibility

Key inclusion criteria
1. Scheduled for cardiac surgery
2. No contra-indication for the use of the pulmonary artery thermodilution method
3. Aged 18 and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria

1. Contra indication for the use of the pulmonary artery thermodilution method
2. Under the age of 18

Date of first enrolment
18/02/2009

Date of final enrolment
18/12/2009

Locations

Countries of recruitment
Netherlands

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

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Sponsor type
Hospital/treatment centre

Website
https://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
Planned publication with BioMed Central.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Boris Cox at b.cox@mumc.nl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No