Level of agreement between Nexfin and PiCCO cardiac output measurements in morbidly obese patients undergoing bariatric surgery

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To validate the Nexfin cardiac output monitor for morbidly obese patients undergoing elective surgery with the PiCCO monitor.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON38632

Source
ToetsingOnline

Brief title
NexPic study

Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Morbid obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac output, Obesity, Perioperative hemodynamics, surgery

Outcome measures

Primary outcome

Level of agreement between Nexfin and PiCCO cardiac output measurements.

Secondary outcome

• Systemic vascular resistance

Study description

Background summary

The non invasive hemodynamic monitoring options in obese patients is limited. Only intermittend bloodpressure measurements are availible. To enlarge the array of options and extend the non invasive monitoring options in the future, we want to validate the Nexfin monitor with the PICCO thermodulition monitor (the gold standard for cardiac output measurements). The end goal is to improve hemodynamic monitoring capabilities for patient safety, and to make non invasive cardiac output measurements availible for future research in obese patients.

Study objective

To validate the Nexfin cardiac output monitor for morbidly obese patients undergoing elective surgery with the PiCCO monitor.

Study design

Prospective observational population study in the St. Lucas Andreas Ziekenhuis, Amsterdam, the Netherlands.

Study burden and risks

The study subject do not have a direct benefit from participating in this study. The burden consist mostly of the chance of complications.
The chance of a complication for placinf a central veneus acces is about 1%.

These are mostly hematomas around the acces site. Other comlications are puncturing the lung or arterie. The comlication rate for these is also about 1 %. All procedures will be done ultrasound guided.
And nog more than three tries will be attempted.
The complication rate for an arterial line is about 1% aswell. This is also for the most part heamatoma at the acces site.
Alle procedures will be doen will the patient is under anesthesia so placement of the lines is not a big burden.

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

- Indication for bariatric surgery
- Informed consent

• Age 18-70 years
• ASA classification I-III

Exclusion criteria

• Cardiac arrhythmia
• Valve replacement
• Inability to place intra-arterial lines for thermodilution measurements

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Nexfin hemodynamic monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-12-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

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	NL45442.100.13