A Prospective, Nonrandomized, Noninterventional Study to Compare Nexfin CO-trek Cardiac Output with Thermodilution Cardiac Output

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Demonstrate that noninvasive monitoring of cardiac output with the ccNexfin System is comparable to that with thermodilution cardiac output.

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

Summary

ID

NL-OMON38805

Source
ToetsingOnline

Brief title
Nexfin/TD Clinical Study

Condition

- Other condition

Synonym
N.A.

Health condition

specifieke aandoeningen zijn niet van belang voor het onderzoek; daar een clinische standaard methode voor cardiac output bepaling aanwezig moet zijn als referentie, zal het onderzoek worden uitgevoerd in high-risk surgery

Research involving
Human

Sponsors and support

Primary sponsor: Edwards Lifesciences BMEYE
Source(s) of monetary or material Support: Edwards Lifesciences LLC

Intervention

Keyword: Cardiac Output, ccNexfin, Comparison, Noninvasive

Outcome measures

Primary outcome

Noninvasive monitoring of CO with the ccNexfin System is comparable to TD as determined by a bias less than 0.6 L/min.

Secondary outcome

Comparability of both methods as determined by Bland-Altman analysis (Bias and Percentage Error). Precision of Nexfin CO-trek versus TD will be determined.

The Pearson correlation coefficient for the CO pairs of both methods will be assessed. In patients where Trendelenburg / reverse Trendelenburg positions are clinically required, changes in CO due to these interventions on hemodynamics will be measured to demonstrate concordance of devices in case of repeated measurement. Fluid administration, use of vasoactive and inotropic drugs will be recorded when available to the Investigator.

Study description

Background summary

Noninvasive measurement of cardiac output using ccNexfin allows monitoring of almost any patient in the OR. Consequently, fluids for individual patients may

be managed more appropriately, leading to less post-operative complications and morbidity.

Study objective

Demonstrate that noninvasive monitoring of cardiac output with the ccNexfin System is comparable to that with thermodilution cardiac output.

Study design

Prospective, nonrandomized, noninterventional validation study.

Study burden and risks

Burden and risks are negligible. The study is not group related.

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

Subjects will be included if they meet the following criteria:
1. Subjects must be at least 18 years of age
2. Subjects must give signed written informed consent
3. Subjects* height and weight must be accurately obtained prior to study start.

Exclusion criteria

Subjects will be excluded if any of these items exist:
1. Aortic or tricuspid valve regurgitation
2. Aortic stenosis or aneurysms
3. History of uncontrolled cardiac arrhythmia
4. Any peripheral vascular disease or conditions such as Raynaud*s disease or Buerger*s disease
5. Insufficient perfusion of the digits
6. Inability to place the finger cuff appropriately due to subject anatomy or condition
7. Known pregnancy
8. Patients being treated with an intra-aortic balloon pump
9. Patient is currently participating in an investigational drug or another device study that clinically interferes with the study endpoints

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2013
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	30-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL44270.018.13