A Prospective, Nonrandomized, Noninvasive Study to Compare Nexfin CO-trek Cardiac Output with Trans-Thoracic Echo Cardiography Cardiac Output

Published: 21-05-2013
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The present study aims to demonstrate that non-invasive determination of CO with ccNexfin is comparable to the CO of the TTE.

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

Summary

ID

NL-OMON38784

Source
ToetsingOnline

Brief title
TTE/Nexfin Clinical Study

Condition

- Other condition

Synonym
N.A.

Health condition

specifieke aandoeningen zijn niet van belang voor het onderzoek; daar het onderzoek in een cardiologische omgeving uitgevoerd zal worden, zullen meeste proefpersonen cardiologische aandoeningen hebben

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac Output, ccNexfin, Comparison, Noninvasive

Outcome measures

Primary outcome

Cardiac output obtained with the ccNexfin system and with TTE and their

comparability as determined by Bland-Altman analysis.

Secondary outcome

Changes in cardiac output obtained with the ccNexfin system and with TTE and

their comparability as determined by correlation / concordance analysis.

Incidence of adverse events will be registered.

Study description

Background summary

Noninvasive measurement of cardiac output using ccNexfin allows monitoring of almost any patient in the operating room. Consequently, fluids for individual patients may be managed more appropriately, leading to less post-operative complications and morbidity.

Study objective

The present study aims to demonstrate that non-invasive determination of CO with ccNexfin is comparable to the CO of the TTE.

Study design

Prospective, non-randomized, non-invasive

Intervention

No intervention for the patients; standing, exercise for the possibly enrolled volunteers.

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

Potential Subjects must:
- be at least 18 years of age
- must give signed written informed consent

Exclusion criteria

Subjects will be excluded if any of these items exist:
1. Aortic 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.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2013
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL43819.094.13