Comparison of heart minute volume measured with the standard method (pulmonalis catheter) with a new method using the arterial wave form in groin or at the wrist in serious sick patients in the intensive care.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22489

Source
NTR

Health condition

Septic Shock or dynamic hemodynamic profiles

Sponsors and support

Primary sponsor: Zaans Medical Centre
Source(s) of monetary or material Support: Zaans Medical Centre

Intervention

Outcome measures

Primary outcome

1. Bias, percision, limits of agreement;

2. Percentage of error, Bland altman plot.

Grouped measurements of cardiac output derived from PAC and waveform analysis are performed in triplets, and averaged. Before and after therapeutic interventions in ICU, before and after fluid challenge, before and after changing inotropes, like vasodialition drugs.

Secondary outcome

N/A

Study description

Background summary

During the progress of organ failure in critical ill patients often it is unclear whether the patient is adequately fluid resuscitated. To facilitate optimal fluid resuscitation cardiac output is measured by either using an invasive pulmonary artery catheter or a less invasive device. A new minimal invasive technique has become available. Cardiac output measured by arterial pressure waveform (APCO) analysis without manual calibration, the FloTrac/VigileoTM system Edwards Lifesciences. Since its launch there have been three software updates. The cardiac output derived from the arterial waveform analysis of the two latest versions showed good agreements when compared to pulmonary artery catheter under stable haemodynamic conditions [1,2]. In septic shock the bias has been improved with introduction of the 1.10 version of the software (unpublished data). Only recently the newest software version has been released (3.02).

The aim of the study is to determine whether cardiac output measurements obtained using APCO are comparable with those obtained using intermitted thermodilution cardiac output in critical ill patients.

Study objective

The aim of the study is to determine whether cardiac output measurements obtained using APCO are comparable with those obtained using intermitted thermodilution cardiac output in critical ill patients.

Study design

Power analysis after 8 patients.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Sinus Rhythm;

2. Septic Shock;

3. Inotropic support including Noradrenalin;

4. PA Catheter;

5. Informed consent.

Exclusion criteria

1. Non sinus rhythm;

2. No informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2009
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-10-2009
Application type:	First submission

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
NTR-new	NL1954
NTR-old	NTR2072
Other	METC Noord Holland : M09-035
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A