

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.

Gepubliceerd: 12-10-2009 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22489

Bron

NTR

Aandoening

Septic Shock or dynamic hemodynamic profiles

Ondersteuning

Primaire sponsor: Zaans Medical Centre

Overige ondersteuning: Zaans Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Bias, precision, 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 vasodilation drugs.

Toelichting onderzoek

Achtergrond van het onderzoek

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/Vigileo™ 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 In septic shock the bias has been improved with introduction of the 1.10 version of the software (unpublished data).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 intermittent thermodilution cardiac output in critical ill patients.

Doel van het onderzoek

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

Onderzoeksopzet

Power analysis after 8 patients.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Sinus Rhythm;
2. Septic Shock;
3. Inotropic support including Noradrenalin;
4. PA Catheter;
5. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Non sinus rhythm;
2. No informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	09-01-2009
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	12-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1954
NTR-old	NTR2072
Ander register	METC Noord Holland : M09-035
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A