# 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.

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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.

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

## Samenvatting

### ID

NL-OMON22489

**Bron**
Nationaal Trial Register

**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, percision, limits of agreement;<br>
2. Percentage of error, Bland altman plot.<br>
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.

# 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/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 In septic shock the bias has been improved with introduction of the 1.10 version of the software (unpublished data).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.

### 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 intermitted 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 |
| Blindering: | 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