

# The role of mean systemic filling pressure and incubator tilt induced etCO2 change for the prediction of fluid responsiveness in neonates - a feasibility study

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Is it feasible to measure mean systemic filling pressure (Pmsf) and  $\Delta$ etCO2 secondary to an incubator tilt maneuver in newborn infants?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON38430

### Source

ToetsingOnline

### Brief title

Prediction of fluid responsiveness in neonates

### Condition

- Heart failures
- Neonatal and perinatal conditions

### Synonym

Hypovolemia, low volume

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** eigen financiering afdeling Neonatologie;UMC St Radboud Nijmegen

## Intervention

**Keyword:** Fluid responsiveness, Incubator tilt, Mean systemic filling pressure, Volume status

## Outcome measures

### Primary outcome

The two study parameters are

- The mean systemic filling pressure (Pmsf), assessed with an extremity occlusion test
- The change in end-tidal carbon dioxide pressure ( $\Delta$ etCO<sub>2</sub>) in response to a incubator tilting maneuver

### Secondary outcome

Not applicable

## Study description

### Background summary

To ensure adequate perfusion and tissue oxygenation in neonates an adequate filling pressure is necessary. In case of hypovolemia, a fluid bolus can be life saving. However, volume expansion (VE) in an already hypervolemic neonate is not without risk and is associated with disturbed neurological outcome, increased prevalence of chronic lung disease and increased mortality. To avoid adverse effects due to excessive fluid overload it is important to be able to accurately predict if a fluid bolus does result in an increase in cardiac output (CO), defined as \*fluid responsiveness\*. Recently, two new methods to predict fluid responsiveness are described in adult patients: the change in end-tidal CO<sub>2</sub> ( $\Delta$ etCO<sub>2</sub>) during passive leg raise (PLR) and the mean systemic filling pressure (Pmsf). Both methods show promising results in adults. However, these findings on fluid responsiveness in adults cannot simply be

extrapolated to neonates, since there is a rather large difference between neonatal and adult physiology. Therefore we want to investigate the feasibility of measuring  $\Delta\text{etCO}_2$  and Pmsf in neonates in this pilot study.

## **Study objective**

Is it feasible to measure mean systemic filling pressure (Pmsf) and  $\Delta\text{etCO}_2$  secondary to an incubator tilt maneuver in newborn infants?

## **Study design**

Prospective feasibility study

## **Study burden and risks**

The procedure of Pmsf is comparable with non-invasive blood pressure measurement. However, the duration of arterial occlusion will be longer, i.e. 30 seconds. This will result in a slight increase in discomfort in comparison with regular non-invasive blood pressure measurement. The incubator tilt maneuver is comparable with the tilting of the incubator and handling of the patient that is performed during daily routine care. The Trendelenburg position is avoided to prevent cerebral hyperperfusion. There are no benefits for the patient related to this feasibility study.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

- Arterial catheter in place, well functioning with the tip positioned in the radial artery or posterior tibial artery (for Pmsf measurement)
- Mechanical ventilation with capnography (for  $\Delta$ etCO<sub>2</sub> assessment)
- Informed consent obtained from parents or representatives
- Steady state as judged by the attending physician

### Exclusion criteria

- Life-threatening congenital defects
- Perinatal asphyxia
- Intraventricular hemorrhage > grade 1
- Central venous catheter or peripheral infusion with administration of (cardiovascular) drugs, that can not be interrupted secondary to vascular occlusion for 30 seconds
- Condition in which an incubator tilt is contraindicated, such as for example external ventricular drainage;
- Condition in which any handling is contraindicated

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2013
Enrollment:	20
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	13-09-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL45608.091.13