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

Published: 13-09-2013
Last updated: 22-04-2024

Is it feasible to measure mean systemic filling pressure (Pmsf) and ΔetCO2 secondary to an incubator tilt maneuver in newborn infants?

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	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 (ΔetCO2) 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 CO2 (ΔetCO2) 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 ΔetCO2 and Pmsf in neonates in this pilot study.

Study objective

Is it feasible to measure mean systemic filling pressure (Pmsf) and ΔetCO2 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

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein zuid 10
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein zuid 10
Nijmegen 6525 GA
NL

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 ΔetCO2 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 of 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