EARLY DETECTION OF SHOCK IN CRITICALLY ILL NEWBORN INFANTS. The impact of advanced hemodynamic monitoring

Published: 12-10-2012
Last updated: 26-04-2024

It is hypothesized that advanced hemodynamic monitoring will result in earlier detection of circulatory failure in critically ill newborn infants compared to clinical assessment of shock, which is the actual standard diagnostic tool in daily...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON37793

Source
ToetsingOnline

Brief title
Early detection of neonatal shock

Condition

- Heart failures
- Neonatal and perinatal conditions

Synonym
circulatory failure, Shock

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: Hemodynamics, Monitoring, Newborn, Shock

Outcome measures

Primary outcome

1. Timing (postnatal age) of diagnosis of circulatory failure (shock)

2. Agreement between objective cardiac output assessment by transpulmonary ultrasound dilution (TPUD) and simultaneously clinically estimated cardiac output (absolute and categorical)

Secondary outcome

Other hemodynamic parameters that will be analyzed are:

- regional oxygen saturation at the level of the brain, kidney, intestines and muscle

- arterial blood pressure

- heart rate

- arterial oxygen saturation

- hemodynamic volumetry

Study description

Background summary

Circulatory failure is a main cause of serious morbidity and mortality in critically ill newborn infants. Early detection of circulatory failure (shock)

is quite a challenge. Many methods of advanced hemodynamic monitoring have been introduced in routine care in critically ill adults and larger children. Most technologies, however, are not applicable in neonates. The hemodynamic status of newborn infants is usually estimated by the interpretation of indirect parameters of cardiac output, such as blood pressure, heart rate, color, urine production et cetera. It has however been shown in adults and larger children that this clinical assessment is inaccurate, irrespective of the level of experience of the clinician. Most clinical signs and symptoms of neonatal circulatory failure are rather subjective with a questionable reproducibility. Comprehensive hemodynamic monitoring could has a reality in neonatal care thanks to advances in medical technology. Our research group has gathered much experience with the validation of transpulmonary ultrasound dilution (TPUD) in many experimental animal studies. This showed that TPUD is applicable in neonates under severe specific circumstances and conditions.

Study objective

It is hypothesized that advanced hemodynamic monitoring will result in earlier detection of circulatory failure in critically ill newborn infants compared to clinical assessment of shock, which is the actual standard diagnostic tool in daily neonatal intensive care practice. Moreover, advanced hemodynamic monitoring offers the unique opportunity to gather information about cardiovascular (path)physiology in newborns.

Study design

Prospective observational cohort study

Study burden and risks

The risks for the newborn infant that participates in this study is negligible, since it concerns a non-therapeutic, prospective observational cohort study in which the patients will be comprehensively hemodynamically monitored with medical equipment that received CE marking. Moreover, the hemodynamic variables acquired with transpulmonary ultrasound dilution and/or near infrared spectroscopy, are blinded for the attending physicians. This implies that clinical decision-making is not different from non-participating patients or daily practice.

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

- Birth weight >=700 grams
- Arterial catheter in place, well functioning with tip adequately positioned in abdominal aorta (umbilical catheter), radial artery or posterior tibial artery
- Central venous catheter in place, non-silicone, well functioning with tip adequately positioned on the junction between right atrium and inferior vena cava or superior vena cava (multi-lumen, when a pause in the continuous intravenous administration of drugs (for example inotropes or vasopressors) is not possible; single-lumen, when the continuous administration of drugs can be stopped for the period of cardiac output measurements, approximately 5-6 minutes)
- Informed consent obtained from parents or representatives

Exclusion criteria

- Infants not meeting eligibility criteria
- Life-threatening congenital defects
- Congenital heart defects, except for patent ductus arteriosus and patent foramen ovale.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2013
Enrollment:	112
Type:	Actual

Medical products/devices used

Generic name:	COstatus - Transpulmonary ultrasound dilution
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-10-2012
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
ClinicalTrials.gov	NCT01550198
CCMO	NL38140.091.12