Norepinephrine for the management of hypotension in premature and full-term neonates

Published: 27-05-2015
Last updated: 14-04-2024

To investigate if norepinephrine is safe and effective in increasing blood pressure and systemic blood flow in premature and full-term neonates with shock and/or hypotension.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Decreased and nonspecific blood pressure disorders and shock
Study type	Observational non invasive

Summary

ID

NL-OMON42050

Source
ToetsingOnline

Brief title
Norepinephrine for hypotension in neonates

Condition

- Decreased and nonspecific blood pressure disorders and shock

Synonym
hypotension, low blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Studie wordt gefinancierd door de afdeling Neonatologie.

Intervention

Keyword: Hypotension, Neonates, Norepinephrine

Outcome measures

Primary outcome

Primary outcome measure is change in blood pressure and systemic blood flow.

Secondary outcome

Secondary outcomes are effects on the cardiac function, effects on the

pulmonary condition, effects on tissue perfusion and adverse effects during

hospitalization.

Study description

Background summary

Hypotension is a common but serious complication in neonates. The primary etiological factors of hypotension are abnormal peripheral vasoregulation and myocardial dysfunction. Severe hypotension is associated with a higher incidence of intraventricular hemorrhage and an adverse neurodevelopmental outcome Because of these potential serious consequences, early and effective treatment is essential to increase the chance of improved neurological outcome and survival.

In case of severe hypotension nonresponsive to fluid resuscitation, initiation of inotropic and/or vasoactive agents are warranted to increase cardiac output, maintain adequate blood pressure and thereby oxygen delivery to the tissue. Dopamine is the most commonly used pharmacological agent in the treatment of newborn hypotension. Another frequently used drug is dobutamine. Nevertheless, failure to sustain adequate blood pressure despite high doses have been reported. Recent findings also suggest that vasopressor resistance can be treated with a brief course of hydrocortisone. However, due to the short- and potential long-term side effects of early hydrocortisone treatment, this might not be the preferred medication.

Norepinephrine can be suggested as an alternative medicine in the treatment of hypotension. In different studies norepinephrine was found to raise blood pressure without adverse effect on organ blood flow. However, it is assumed

that use of norepinephrine can lead to an increase of the total peripheral vascular resistance resulting in decreased cardiac output and tissue perfusion, hypertension, tachycardia, decreased myocardial oxygen delivery and tissue necrosis. Nevertheless, at our NICU norepinephrine has been used for the last years in both premature as full-term neonates without known adverse events related to the use of norepinephrine.

In adults norepinephrine has recently been recommended as the first-choice vasopressor agent to correct hypotension. However, only limited information regarding the clinical effects of norepinephrine in the newborn is available. Since pharmacokinetics and pharmacodynamics are very different in children and adults norepinephrine needs to be studied in this specific population.

Study objective

To investigate if norepinephrine is safe and effective in increasing blood pressure and systemic blood flow in premature and full-term neonates with shock and/or hypotension.

Study design

A prospective cohort study with a total duration of 1 year conducted at the neonatal intensive care unit of the Radboudumc in the Netherlands.

Study burden and risks

Burden
All infants participating in the study are subjected to routine neonatal intensive care and hemodynamic management is performed according the actual protocol for neonatal shock/hypotension. Norepinephrine is one of the several cardiovascular drugs that are routinely used on the neonatal intensive care unit. This study does require an extra echocardiography, before and after initiation of treatment with norepinephrine.

Benefits and risks
Norepinephrine may increase the blood pressure and systemic blood flow, improve the cardiac function and thereby enhance oxygen delivery to the tissue. These beneficial effects may improve neurodevelopmental outcome. On the other hand, it is assumed that use of norepinephrine can lead to an increase of the total peripheral vascular resistance resulting in decreased cardiac output and tissue perfusion, hypertension, tachycardia, decreased myocardial oxygen delivery and tissue necrosis.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Hof van St. Jan 6
Utrecht 3512BX
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Hof van St. Jan 6
Utrecht 3512BX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1) A gestational age between 24+0 and 42+0 weeks
2) <1 month old
3) Hypotension* as indication for treatment with norepinephrine
* Hypotension is defined as: mean arterial blood pressure < total number of completed weeks of gestational age

Exclusion criteria

1) Chromosomal defects
2) Major congenital malformations that increase the risk of death or adverse neurodevelopmental outcome
3) Infants with hypotension during treatment with extracorporeal membrane oxygenation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-05-2015
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	NL52305.091.15