Heart rate and Oxygen saturation in Term Infants Study

Published: 03-11-2015
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To provide normative data and reference values for oxygen saturation and heart rate in healthy newborns the first 48 hours of life.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42428

Source
ToetsingOnline

Brief title
HOTIS

Condition

- Other condition

Synonym
Neonatal transition problems, short-term drop in oxygen saturation and heart rate

Health condition

Neonatale transitie problematiek

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Het onderzoek is eigen research waarbij de

kosten die ontstaan worden betaald uit de algemene middelen van de vakgroep Kindergeneeskunde van het Amphia ziekenhuis.

Intervention

Keyword: Heart rate, Infant, newborn, Oximetry, Oxygen saturation, Pulse

Outcome measures

Primary outcome

The main endpoints are the distribution and percentile scores of oxygen saturation and heart rate. Also the frequency and significance of desaturations and episodes of bradycardia are main endpoints

Secondary outcome

The secondary objective of this study is to investigate the differences in normal ranges of vital signs between newborns with differences in obstetric history (i.e. caesarean delivery, small for gestational age, large for gestational age, late prematurity) and between periods of feeding and non-feeding.

Study description

Background summary

Pulse oximetry is frequently used in newborn care to monitor vital signs for different reasons. Marked desaturations <92% or bradycardia <80 bpm are often seen in term infants during monitoring, without obvious relation to the reason of monitoring and without clinical consequence. In the literature little to no studies describe reference values for continuous measurements of oxygen saturation and heart rate in healthy term infants.

Study objective

To provide normative data and reference values for oxygen saturation and heart

rate in healthy newborns the first 48 hours of life.

Study design

Prospective cross-sectional study

Study burden and risks

The study requires for the study subjects to be connected to a monitoring device using a sensor placed on the left arm or foot. No burden or adverse events will be associated with participation. For the infants enrolled in this study there is no added individual benefit. They do, however, participate in setting normal values for future use in other infants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Newborn infants in the first 6 hours of life
- Gestational age 35 weeks or above

Exclusion criteria

- Gestational age <35 weeks
- Medical indication for monitoring vital signs
- Any known cardiac or chromosomal defect
- Any (antenatally or postnatally) suspected cardiac defect
- Absence of written informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-11-2015
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL54229.101.15