Pulse oximetry screening for congenital heart disease in community based midwifery care in the Netherlands; a feasibility study

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To investigate whether it is feasible to perform a large national implementation study in which community based midwives in the Netherlands use a pulse oximeter for screening newborns for CHD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON40229

Source
ToetsingOnline

Brief title
Pulse Oximetry Leiden Screening Study (POLS study)

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
congenital heart defects

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Covidien, Ireland, Dublin,Covidien;Ireland;Dublin

Intervention

Keyword: congenital heart defect, neonate, pulse oximetry, screening

Outcome measures

Primary outcome

the percentage of low risk infants that was screened for congenital heart

disease using pulse oximetry

Secondary outcome

problems identified in use of PO in home setting, problems identified with

referral logistics, sensitivity, specificity, positive and negative predictive

value of the screening method, the percentage of false positive referrals,

other pathology found with the screening, acceptability for mothers

Study description

Background summary

Congenital heart disease (CHD) is the most common group of congenital malformations and is a leading cause of infant death in the developed world. Early detection of severe CHD (SCHD) in both pre- and postnatal period is vital for the prognosis. Despite antenatal echocardiography screening and physical examination after birth , SCHD is still often missed. Pulse Oximetry (PO) has now been recommended by the American Association of Pediatrics as a screening tool for cyanotic CHD in low risk infants after birth. However, the perinatal care for low-risk infants is unique as deliveries are supervised by community-based midwives where the births take place at home, in a birth clinic or in hospital. This accounts for approximately 30% of all deliveries. Besides of the logistic challenge, it remains uncertain whether in the Netherlands similar benefits and false positive referrals of CHD screening

could be anticipated and if it weighs against the costs of providing all midwives with a pulse oximeter.

Study objective

To investigate whether it is feasible to perform a large national implementation study in which community based midwives in the Netherlands use a pulse oximeter for screening newborns for CHD.

Study design

prospective non-randomized feasibility study

Intervention

Pre ductal (right hand) and post ductal (right foot) pulse oximetry 1 hour post delivery.
When saturation is lower than 90% the screening test is considered positive. If the saturation is between 90 en 95% and/or the difference between pre and post ductal saturation is more than 3%, the screening test will be repeated after one hour. If the saturation is <95% and/or the difference between pre and post ductal saturation is more than 3% at that measurement, the screening is considered positive.
When saturation is 95% or higher and the difference between pre and post ductal saturation is 3% or less, the screening test will be repeated at day 2 or 3 of the infant's life. If the saturation is 95% or higher and the difference between pre and post ductal saturation is 3% or less at that last measurement, the screening is considered negative and there will be no interventions.

In case of a positive screening the infant will be referred to the Leiden University Medical Center (LUMC) on the same day. In the LUMC physical examination and, in case of persistant hypoxia, an echocardiography will be done by a pediatrician/neonatologist and pediatric cardiologist.

Study burden and risks

No expected risks for the neonates
Possible burden: increased distress in parents and/or midwives supervising births caused by false-positive referrals

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All term infants born in regio Leiden in period of 01-10-2013 to 30-09-2014

Exclusion criteria

Pulse oximetry monitoring as part of the care during admittance in hospital

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2013
Enrollment:	3420
Type:	Actual

Medical products/devices used

Generic name:	pulse oximeter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-09-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	09-10-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-02-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	31-03-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26133
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45190.058.13
OMON	NL-OMON26133