

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Congenital cardiac disorders
<b>Study type</b>	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 persistent 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**

### **Public**

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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: NTR

Title:

### In other registers

Register	ID
CCMO	NL45190.058.13
OMON	NL-OMON26133