Pulse oximetry screening for critical congenital heart disease and relevant newborn pathology in the Netherlands

Published: 08-01-2015
Last updated: 21-04-2024

To assess the accuracy and cost-effectiveness of PO screening for CCHD in the Dutch perinatal care system.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43684

Source
ToetsingOnline

Brief title
Pulse Oximetry screening Leiden-Amsterdam Region study
POLAR study

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Neonatal respiratory disorders

Synonym
congenital heart defects

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Covidien, Dublin, Ireland,Covidien;Dublin;Ireland

Intervention

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

Outcome measures

Primary outcome

In this study the primary end point will be the accuracy of PO screening for

CCHD. The accuracy is embodied in the sensitivity, specificity, false positive

rate, false negative rate, positive and negative predictive value.

Secondary outcome

Cost-effectiveness

Problems identified in the use of PO in home setting

Problems identified with referral logistics

Other pathology detected with screening with PO

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 critical CHD (CCHD) in both pre- and postnatal period is vital for
the prognosis. Despite antenatal echocardiography screening and physical examination after birth , CCHD 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. The feasibility of PO

screening in the Dutch system was proved in a feasibility study in Leiden. A larger implementation study is needed to assess the accuracy and cost-effectiveness of PO screening for CCHD.

Study objective

To assess the accuracy and cost-effectiveness of PO screening for CCHD in the Dutch perinatal care system.

Study design

Prospective, non-randomized implementation study

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
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All infants born in the Amsterdam-Leiden region

Exclusion criteria

pre and post ductal pulse oximetry measurements for monitoring;
Ecocardiographie performed post natally

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2015
Enrollment:	20000
Type:	Actual

Ethics review

Approved WMO

Date:	08-01-2015
Application type:	First submission

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-03-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-04-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-07-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-07-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-08-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-09-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-10-2015
Application type:	Amendment

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	12-08-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL51644.058.14