POLS study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26133

Source
NTR

Brief title
POLS study

Health condition

congenital heart defects, screening, homebirth
Aangeboren hartafwijkingen, screeningen, thuisbevalling

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Covidien (Dublin, Ireland) gave financial support for this study through a researh grant.

Intervention

Outcome measures

Primary outcome

Percentage of term infants born in the Leiden region in the study period that was screened for congenital heart defects with pulse oximetry

Secondary outcome

Problems identified in the use of PO in home setting; Problems identified with referral logistics; Sensitivity and specificity of the screening; Positive and negative predictive value of the screening
Percentage of false positive referrals
Other pathology found with screening with PO
Acceptability of mothers

Study description

Background summary

The feasbility of neonatal screening for critical congenital heart defects is assessed in the Leiden region. Pre and post ductal oxygen saturation is measured in term neonates with a pulse oximeter at least one hour after birth and at day two or three. The screening takes place at home or in the hospital. Primary endpoint will be the percentage of term neonates born in the Leiden region in the study period that is screened for critical congenital heart defects

Study objective

Screening for congenital heart defects using pulse oximetry is feasible in the Netherlands

Study design

at least one hour after birth at day one and at day two or three (day one is day of birth)

Intervention

pre and post ductal oxygen saturation measurement with pulse oximeter at least one hour after birth and at day two or three (with day of birth counting as day one)

Contacts

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Scientific
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Eligibility criteria

Inclusion criteria

Term neonate born in Leiden region

Exclusion criteria

Monitored with pulse oximetry

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-10-2013
Enrollment:	3000
Type:	Anticipated

Ethics review

Positive opinion
Date: 03-02-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40229
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4212
NTR-old	NTR4365
CCMO	NL45190.058.13
OMON	NL-OMON40229

Study results