Implementatiestudie screening op aangeboren hartafwijkingen in Nederland

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25440

Source
NTR

Brief title
POLAR study

Health condition

Critical congenital heart defects
Potential threatening pathology causing hypoxemia in the neonate, such as persistent pulmonary hypertension, infection or sepsis.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Covidien, Dublin, Ireland

Intervention

Outcome measures

Primary outcome

Accuracy of the screening for critical congenital heart defects: sensitivity, specificity, false positive rate, positive predictive value, negative predictive value.

Secondary outcome

Cost-effectiviness of the screening;

Detection of other possible life threatening pathology, such as persistent pulmonary hypertension of the newborn, infection, sepsis, non-critical congenital heart defects;

Problems identified in the use of PO in home setting;

Problems identified with referral logistics

Study description

Background summary

To assess the accuracy and cost-effectiveness of pulse oximetry screening for critical congenital heart defects in the Dutch perinatal care system, we perform an implementation study in the Leiden-Amsterdam region.

Study objective

Pulse oximetry screening for critical congenital heart defects in the Netherlands is intermediate sensitive, highly specific and cost-effective.

Study design

Preparation: 01-12-2014 - 01-05-2015

Starting phase: 01-05-2015 - 01-08-2015

Inclusion: 01-08-2015 - 01-02-2017

Analysis: 01-02-2017 - 01-12-2017

Intervention

Pulse oximetry reading at least one hour after birth at right hand and either foot.

Pulse oximetry reading at day two or three at right hand and either foot.

Contacts

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Eligibility criteria

Inclusion criteria

Infants born in the Amsterdam-Leiden region.

Exclusion criteria

Infants where pre and post ductal pulse oximetry is performed for at least 24 hours for monitoring.

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:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	20000
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4681
NTR-old	NTR4833
Other	: METC P14.307

Study results