Pulmonary Hypertension in preterm children born at gestational age <30 weeks: Prevalence, risk factors and outcome.

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Is to identify the incidence and prevalende of PH in premature born infants. In addition we will identify possible risk factors for the development of PH and we want to determine the prognosis and survival of these patients. PrimaryTo determine the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44035

Source
ToetsingOnline

Brief title
Neolifes-Heart

Condition

- Other condition
- Heart failures
- Neonatal respiratory disorders

Synonym
Pulmonary Hypertension; High pressure in the lungs

Health condition

Pulmonale hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bronchopulmonary Dysplasia, Incidence, Outcome, Pulmonary Hypertension

Outcome measures

Primary outcome

The presence of PH (incidence and prevalence).

Secondary outcome

Morbidity, Mortality: Quality of life questionnaire and survival.

Maternal factors: mode of conception, delivery, preterm premature rupture of membranes, maternal disease history, illnesses during gestation, tabacco and medication use.

Perinatal variables: slow growth patterns in utero, prenatal echo findings, PROM, chorionamniotis, oligoamnion, birth events, placental histology.

Neonatal variables: development of BPD, low birth weight, gestational age, skull circumference, pulmonary and artficial ventilation variables, oxygen need, presence of PDA, medication, infections, renal function, complications (NEC), slow growth at GA 36wks and at discharge.

other: demographics, slow growth, admissions, medication, feeding, neurological

development, respiratory symptoms, lung clearing index.

Study description

Background summary

The development is not complete in premature born children. For example, the lungs are not fully developed. This is associated with shortness of breath and an increased oxygen need. Some of these children will need ventilation support and develop the condition Bronchopulmonary dysplasia (BPD). BPD is considered with lung injury and more than 28 days of ventilation support. These children have more need for oxygen and are extra sensitive for infections.

In the present era, BPD most often occurs in extremely premature infants born at 24*28 weeks* post menstrual age, who have showed less severe acute respiratory symptoms and require less respiratory support than BPD patients have traditionally had in the past. Histological examination of these *new BPD* patients suggests that the extreme preterm birth in combination with perinatal lung injury affects the normal growth of the lung development, resulting in disrupted vascular growth and impaired alveolarization, which could result in PH, a high blodd pressure in the lungs. The causal relation among prenatal factors, prematurity, BPD and PH are not fully known yet.

In premature newborns, < 30 weeks, the prevalence of BPD has been estimated to be 30-60% , while the prevalence of occurrence of PH received significantly less attention and estimates vary from 18% in the total group and up to 30% in the BPD-group and 50% in the severe BPD-group. The development of PH complicates the postnatal course of extreme premature infants. Both early and late PH are associated with poor outcomes among preterm infants, with and without BPD. Recent reports suggests that morbidity and late mortality of PH in the *new BPD* is high, with up to 48% mortality 2 years after diagnosis of PH.

The pathogenesis of BPD is complex and known risk factors for the development of severe BPD includes maternal and neonatal factors, such as childbearing history, male gender, smoking mother during pregnancy, chorioamnionitis, low-birth-weight, gestational age, cholestasis and acute lung injury by high ventilator settings. Risk factors for the development of PH in extreme preterm infants are not well defined.

Knowledge of prevalence and risk factors of PH in extreme premature infants will allow evidence-based screening guidelines for the infants. Also

potentially leading to prevention of this complicating condition in the future, since an earlier intervention will be possible under guidance of known risk factors. Early detection will lead to early and thus potentially better treatment of PH in preterm born infants.

Study objective

Is to identify the incidence and prevalende of PH in premature born infants. In addition we will identify possible risk factors for the development of PH and we want to determine the prognosis and survival of these patients.

Primary

To determine the incidence and prevalence of PH in these premature infants (with and without BPD) in the first year of life,

Secundary

To define risk factors for the development of PH in these infants during the first 2 years of life.

Other:

To characterize morbidity, quality of life and mortality associated with PH in these infants during the first 2 years of life.

Study design

Study design: Cohort study. Inclusion 2015-2018,
neonatology/poli/functioncenter UMCG
participants: About 100-120 children a year born after <30 weeks and/or <1000 grams are hospitalized at the department of Neonatology UMCG. Most children are born in the UMCG, however most mothers were redirected to the UMCG with preterm birth. After several weeks at the neonatal intensive care, the children will be dismissed to several regional hospitals. Frequently to Post-IC/High Cares in Martini hospital and MCL, or to other hospitals in the region. After dismission, the children will be seen at the UMCG for standardized care at: 6, 12 and 24 months corrected age.

For Neolifes-Heart echocardiography and transcutaneous oxygen measurement will be performed at the following moments: 1) first week after birth, 2) 3 months corrected age, 3) 12 months corrected age.

Study burden and risks

The total burden of the patients are kept as low as possible. Most of our measurment moments are at the same time as the moments of standardized care. One measurement moment will not be at the same time as the standardized care, this moment will take place 3 months corrected age.
Furthermore, there are no risks of burden for patients and/or their parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All premature infants, admitted at the neonatology UMCG, born <30 weeks or birth weight < 1000 gram, who participate in NeolifeS

Exclusion criteria

no informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2016
Enrollment:	165
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL53577.042.15