Neurosis.

No registrations found.

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

Summary

ID

NL-OMON29190

Source
NTR

Health condition

Randomised controlled trial
Preterm infants
Inhaled corticosteroids
Bronchopulmonary dysplasia

Gerandomiseerd gecontroleerd onderzoek
Prematuur geboren kinderen
Inhalatiecorticosteroïden
Bronchopulmonale dysplasie

Sponsors and support

Primary sponsor: Neurosis Study Center, Prof. Dr. med. Christian-F. Poets en PD. Dr. med Dirk Bassler, MSc Medical University - Tuebingen Germany
Neurosis study Center, neurosis.studycoordinator@med.uni-tuebingen.de
Source(s) of monetary or material Support: Neurosis Study Center Tuebingen

Intervention

Outcome measures

Primary outcome

The primary outcome is defined as a combination of BPD or death at 36 weeks gestational age.

Secondary outcome

1. Neurodevelopmental outcomes at 18 - 22 months;

2. Adverse treatment effects;

3. Mortality at 36 weeks gestationale age;

4. BPD incidence at 36 weeks gestational age;

5. Duration of positive pressure respiratory support or supplemental oxygen.

Study description

Background summary

Background of the study:

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Survival of extremely low birth weight (ELBW) infants has improved in recent decades, however BPD remains a major health care problem. BPD is a chronic lung disease that occurs in premature infants. BPD not only contributes to the mortality of preterm infants but is also associated with impaired psychomotor outcome in ELBW survivors. A number of approaches followed in preventing or treating BPD have been evaluated in the context of controlled studies. Among the interventions studied are antenatal and postnatal corticosteroids Systemic postnatal corticosteroid treatment is perhaps the most controversial approach known in BPD care. Several reports on the adverse effects of dexamethasone on growth and neurodevelopmental outcomes appeared, thus the widespread use of systemic postnatal steroids was replaced by almost complete avoidance of this form of therapy. Nevertheless, the incidence of ELBW survivors with BPD is increasing and new modalities for prevention and treatment need to be explored. Inhaled corticosteroids have been established as the first-line of treatment in adults and children with persistent asthma, the most common chronic inflammatory disease. As in asthma, the biological rationale of corticosteroid therapy in infants with evolving or established BPD is based on its anti-inflammatory properties. Some trials concerning inhaled corticosteroids did not prevent BPD, but was associated with a lower use of systemic glucocorticoid therapy and mechanical ventilation. One study with Inhaled steroids resulted in a significantly higher success rate in extubation within the first 2 weeks of life and a more pronounced improvement in lung compliance. A study to evaluate the efficacy of inhaled corticosteroids seems to be justified. The hypothesis of this study is that early prophylactic inhalation of budesonide reduces the absolute risk of BPD or death in

preterm infants born <28 weeks gestational age by 10%.

Objective of the study:

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Primary objective - Survival without BPD at 36 weeks gestational age (GA) Secondary objectives - Neurodevelopment at a corrected age of 18-22 months - Adverse treatment effects - Mortality at 36 weeks gestational age - BPD incidence at 36 weeks gestational age - Duration of positive pressure respiratory support or supplemental oxygen.

Study design:

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Randomised placebo-controlled, multicentre clinical trial.

Study population:

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Preterm infants born between 23 0/7 and 27 6/7 weeks gestational age (GA).

Intervention:

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Within 2 years 850 infants of 23-27 weeks GA will be randomised during the first 12 hours of life to Budesonide (BS) of placebo to prevent BPD. Study drugs will be administered via Aerochamber and continued until infants are either off supplementary oxygen and poitive pressure support of have reached a GA of 32 O/7 weeks regardless of ventilatory status.

Primary study parameters/outcome of the study:

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The primary outcome is defined as a combination of BPD or death at 36 weeks gestational

age.

Secundary study parameters/outcome of the study:

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- Neurodevelopmental outcomes at 18 - 22 months; - Adverse treatment effects; - Mortality at 36 weeks gestationale age; - BPD incidence at 36 weeks gestational age; - Duration of positive pressure respiratory support or supplemental oxygen.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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Inflammation is central to the development of BPD. Corticosteroids (CS) have antiinflammatory properties and early inhalation of CS may allow for beneficial local effects on the pulmonary system with a lower risk of undesirable systemic side effects.

Study objective

The hypothesis of this study is that early prophylactic inhalation of budesonide reduces the absolute risk of BPD or
death in preterm infants born <28 weeks gestational age by 10%.

Study design

1. 36 weeks gestational age;

2. 22 months.

Intervention

Within 2 years 850 infants of 23-27 weeks GA will be randomised during the first 12 hours of life to Budesonide (BS) or placebo
to prevent BPD. Study drugs will be administered via Aerochamber and continued until infants are either off supplementary
oxygen and poitive pressure support of have reached a GA of 32 O/7 weeks regardless of ventilatory status.

Contacts

Public
R.K. Kornelisse
Rotterdam
The Netherlands
+31 (0)10 7036077
Scientific
R.K. Kornelisse
Rotterdam
The Netherlands
+31 (0)10 7036077

Eligibility criteria

Inclusion criteria

1. Gestational age of 23 0/7-27 6/7 weeks;

2. Postnatal age < 12 hours;

3. Necessity for any form of positive pressure
support (mechanical or nasal ventilation or CPAP);

4. Singleton or second born in case of multiple pregnancy;

5. Parental consent for participation.

Exclusion criteria

A clinical decision not to administer therapies (infant not considered viable), dysmorphic features or congenital
malformations that adversely affect life expectancy or neurodevelopment and known or suspected congenital
heart disease (not including a persistent ductus arteriosus and/or an atrial septum defect). The clinical
assessment of dysmorphic features, congenital malformations, suspected congenital heart disease and the
decision to exlude an infant for the afore mentioned reasons will be left to the discretion of the attending

physician.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38202
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3728
NTR-old	NTR3891
CCMO	NL35679.078.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38202

Study results

Summary results
N/A