Aerosolised salbutamol in two doses as a treatment for preterm infants with developing bronchopulmonary dysplasia.

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Is a higher dose of aerosolised salbutamol as a treatment for preterm infants suspected for developing BPD more effective than a lower dose on short-term clinical effects?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON33377

Source
ToetsingOnline

Brief title
Salbutamol as a treatment for developing BPD

Condition

- Neonatal respiratory disorders

Synonym
Chronic Lung Disease (CLD) and Bronchopulmonary Dysplasia (BPD)

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: GEEN

Intervention

Keyword: aerosol, bronchopulmonary dysplasia, Premature infants, salbutamol

Outcome measures

Primary outcome

Main study endpoint is the fall in serum potassium.

Secondary outcome

Secondary parameters are heart rate, level of oxygen supplementation,

respirator settings/height of the CPAP-flow, behaviour and dyspnea of the child

during inhalation, saturation and events of apnea.

Study description

Background summary

BPD remains a major cause of morbidity and mortality among premature infants (< 37 weeks PMA). The incidence increases as birth weight decreases. Clinical features of BPD are hypoxemia, need for oxygen therapy and need for ventilatory support. The pathophysiology is characterised by decreased lung compliance, increased airway resistance and bronchospasms. Bronchodilators as salbutamol show improvements in saturation, tidal volume, compliance and resistance. It remains unclear in which dosage salbutamol should be prescribed. Presumably the dose-related effect is responsible for the differences in (the satisfaction about) the use of aerosolised salbutamol, however, among NICUs in the Netherlands there is no consensus regarding the dosage. Therefore we would like to start a pilotstudy to compare dose-related effect.

Study objective

Is a higher dose of aerosolised salbutamol as a treatment for preterm infants suspected for developing BPD more effective than a lower dose on short-term clinical effects?

Study design

Double-blind randomised cross-over trial, a pilot study.

Intervention

One group receives on the first day salbutamol 0.1 mg/kg and 0.5 mg/kg on the second, given 4 times a day. The other group receives 0.5 mg/kg on day one and 0.1 mg/kg on day two.

Study burden and risks

A benefit for infants is the possible association of a better clinical condition using a higher dose of salbutamol. Health risks or any other burden associated with participation are not expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants suspect for developing BPD (> 35 wk PMA) who receive ventilatory support and/or oxygen therapy > 21% and clinically suspected of developing BPD.

Exclusion criteria

Neonates with major congenital malformations, neonates with a life expectancy of less than 72 hours, neonates who receive potassium supplementation.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Salbutamol
Generic name:	Salbutamol 5=1 PCH
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-02-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-03-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
EudraCT	EUCTR2009-010381-30-NL
CCMO	NL27073.075.09