Open lung positive pressure ventilation in neonatal respiratory distress syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22682

Source
Nationaal Trial Register

Brief title
N/A

Health condition

respiratory distress syndrome (RDS), mechanical ventilation

Sponsors and support

Primary sponsor: Emma Children's Hospital AMC, Department of Neonatology

Intervention

Outcome measures

Primary outcome

Oxygenation.

Secondary outcome

1. Time to extubation;

2. Incidence of air leaks;

3. Incidence of hypotension;

4. Incidence of treatment failure.

Study description

Background summary

Secondary lung injury by mechanical ventilation is considered an important risk factor in the development of bronchopulmonary dysplasia (BPD) in preterm infants. Preventing atelectasis and alveolar overdistension (open lung) might reduce the risk for BPD. This open lung ventilation strategy has so far only been used during high-frequency ventilation. Animal studies showed that this approach is also feasible during positive pressure ventilation. This pilot study tries to confirm these findings in preterm infants with RDS, as a first step to a large multicenter randomized controlled trial exploring the long term outcome parameters of open lung positive pressure ventilation.

Study objective

We hypothesize that alveolar recruitment and stabilization (open lung) is feasible during positive pressure ventilation of preterm infants and improves gas exchange compared with conventional positive pressure ventilation.

Study design

N/A

Intervention

Patients will be randomized to receiving either open lung or conventional positive pressure ventilation. During open lung ventilation, collapsed alveoli will be actively recruited and stabilized with sufficient airway pressures. In addition, tidal volumes will be reduced as much as possible, while using high ventilatory rates. During conventional ventilation patients will receive the standard of care using a positive end-expiratory pressure of 5 cmH2O and a tidal volume between 4-7 ml/kg.

Contacts

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Eligibility criteria

Inclusion criteria

1. Gestational age between 27 0/7-34 0/7;

2. Postnatal age < 12 h;

3. Mechanical ventilation for RDS;

4. Informed consent.

Exclusion criteria

1. Small for gestational age (less than P3);

2. Persistent pulmonary hypertension;

3. Congenital malformations;

4. Severe septic shock;

5. Air leak syndrome;

6. Surfactant therapy prior to inclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2006
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	15-12-2005
Application type:	First submission

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	NL507
NTR-old	NTR549
Other	: N/A
ISRCTN	ISRCTN78613200

Study results

Summary results
N/A