Open lung positive pressure ventilation in neonatal respiratory distress syndrome.

Gepubliceerd: 15-12-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22682

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

respiratory distress syndrome (RDS), mechanical ventilation

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Oxygenation.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Postnatal age < 12 h;

3. Mechanical ventilation for RDS;

4. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-01-2006
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-12-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL507
NTR-old	NTR549
Ander register	: N/A
ISRCTN	ISRCTN78613200

Resultaten

Samenvatting resultaten
N/A