

Open lung positive pressure ventilation in neonatal respiratory distress syndrome

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/08/2009	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised open label active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory Distress Syndrome (RDS)

Interventions

Patients will be randomised to receiving either open lung or conventional positive pressure ventilation. During open lung ventilation, collapsed alveoli will be actively recruited and stabilised 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 cm H₂O and a tidal volume between 4-7 ml/kg.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Oxygenation

Key secondary outcome(s))

1. Time to extubation
2. Incidence of air leaks
3. Incidence of hypotension
4. Incidence of treatment failure

Completion date

01/02/2007

Eligibility

Key inclusion criteria

1. Gestational age between 27^{0/7} - 34^{0/7} weeks
2. Postnatal age <12 hours
3. Mechanical ventilation for RDS
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Small for gestational age (<P3)
2. Persistent pulmonary hypertension
3. Congenital malformations
4. Severe septic shock
5. Air leak syndrome
6. Surfactant therapy prior to inclusion

Date of first enrolment

09/01/2006

Date of final enrolment

01/02/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC), Emma Children's Hospital (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009		Yes	No