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Open lung positive pressure ventilation in neonatal respiratory distress syndrome

Submission date	Recruitment status	[_] Prospectively registered
14/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2009	Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Oxygenation

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

Overall study start date
09/01/2006

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

Age group
Neonate

Sex
Both

Target number of participants
30

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)

Sponsor details
Department of Neonatology
Amsterdam
Netherlands
-

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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