# Open lung positive pressure ventilation in neonatal respiratory distress syndrome

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
14/02/2006		☐ 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

#### Contact name

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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

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#### 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