# Gerandomiseerde studie naar het monitoren van longfunctie bij de opvang van te vroeg geborenen bij de geboorte

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON23993

**Source**
NTR

**Brief title**
MONitoR

**Health condition**

prematuriteit- prematurity
resuscitatie-resuscitation

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum, Leiden, The Netherlands
**Source(s) of monetary or material Support:** The Laerdal Foundation for Acute Medicine
Fisher & Paykel Healthcare Limited
Leiden University Fund (LUF/Den Dulk Moermans Fonds

### Intervention

### Outcome measures

**Primary outcome**

The proportion of tidal volumes delivered during manual PPV to an infant within the target range of safe tidal ventilation. The target range of adequate tidal volume is defined as 4-8 mL/kg.

**Secondary outcome**

- Rates of endotracheal intubation in the first 24 hours after birth

- The need for circulatory support over first 24 hours (inotropes and fluid boluses)

- Incidence of air leak (pneumothorax, pulmonary interstitial emphysema,or pneumomediastinum) in the first 72 hours, reported by a radiologist masked to the intervention.

- Incidence of abnormal cranial ultrasound findings (i) all intraventricular haemorrhage, (ii) severe – ie. Papile grade III and IV intraventricular haemorrhage, (iii) periventricular leukomalacia

- Duration of endotracheal (ET) ventilation (hours).

- Duration of nasal CPAP (hours).

- Duration of supplemental oxygen therapy (hours)

- Total duration of assisted ventilation (ET, CPAP) in hours

- Incidence of bronchopulmonary dysplasia (BPD) at 36 weeks corrected gestational age defined as the need for supplementary oxygen and/or any form respiratory support. The severity of BPD will be assessed as proposed by Jobe et al.34 and oxygen reduction test will be performed in case of moderate BPD as described by Walsh et al35.

- Neonatal mortality - death before discharge from hospital.

- Composite outcome of death or BPD

# Study description

**Background summary**

Extremely preterm infants often fail to establish efficient gas exchange independently in the delivery room (DR) and many receive mask ventilation or tracheal intubation and mechanical ventilation. However, immediately after birth the immature lung is highly vulnerable to injury.

Achieving effective manual ventilation can be difficult because most clinicians are not aware

when mask leak or airway obstruction occur. With variable leaks, variable tidal volumes are delivered that may be either inadequate or excessive causing lung injury. Traditionally, adequacy of ventilation during positive pressure ventilation (PPV) in the DR is assessed by adequate chest rise and an increase in heart rate. Recently, it has been demonstrated that the use of a respiratory function monitor (RFM) can guide PPV in the DR, but data from large trial are lacking. The aim of this multicenter RCT is to test the hypothesis that observing the data and waveforms displayed on an RFM during the provision of PPV to preterm infants at birth will increase the proportion of tidal volumes within a predefined “safe range” of 4 – 8 mls/kg.

320 Infants between 24-27 weeks of gestation will be be randomised to either have the RFM visible or covered. Other than allocation of the visible or masked RFM, all other resuscitative measures (e.g. intubation, external cardiac massage, administration of oxygen and other drugs) will be at the discretion of the staff involved, following local protocols.

Primary outcome is the proportion of tidal volumes delivered during manual PPV to an infant within the target range of safe tidal ventilation. The target range of adequate tidal volume is defined as 4-8 mL/kg.
Participating centers:

1. Leiden University Medical Center, Leiden, the Netherlands

2. Department of Newborn Research, Royal Women’s Hospital, Melbourne, Australia

3. Maternal & Children’s University Hospital La Fe, Valencia, Spain

4. Intensive Care Pediatrics, V.Buzzi Children's Hospital, Milan, Italy

5. Karolinska University Hospital and Karolinska Institute, Stockholm, Sweden

## Study objective

To test the hypothesis that observing the data and waveforms displayed on an respiratory function monitor during the provision of positive pressure ventilation to preterm infants at birth will increase the proportion of tidal volumes within a predefined “safe range” of 4 – 8 mls/kg.

## Study design

immediately after birth- discharge

## Intervention

At birth positive pressure ventilation will be given with or without the guidance if a respiratory function monitor. The display of the monitor will be visible or covered.

# Contacts

**Public**
Leiden University Medical Center (LUMC), J6-S, Department of Pediatrics,
P.O. Box 9600
Arjan B. Pas, te
Leiden 2300 RC
The Netherlands
+31 (0)71 5262909
**Scientific**
Leiden University Medical Center (LUMC), J6-S, Department of Pediatrics,
P.O. Box 9600
Arjan B. Pas, te
Leiden 2300 RC
The Netherlands
+31 (0)71 5262909

# Eligibility criteria

## Inclusion criteria

Infants born will be included in this study if they are between 24 and 27 completed weeks gestation receiving PPV for resuscitation at birth and do not have a known abnormality which might interfere with breathing.

## Exclusion criteria

Infants will be excluded from the final analysis if they are found to have a congenital abnormality or condition that might have an adverse effect on breathing or ventilation, including: congenital diaphragmatic hernia, tracheo-oesophageal fistula or cyanotic heart disease.

# Study design

## Design

Study type: Observational non invasive

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-09-2013 |
| Enrollment: | 320 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 02-08-2013 |
| 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 | NL3939 |

| Register | ID |
| --- | --- |
| NTR-old | NTR4104 |
| Other | METC LUMC : P 12.295 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A