

# 'Early selective treatment of RDS with Curosurf guided by lamellar body counts

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/03/2006   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>08/05/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>28/06/2011       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Henrik Verder

**Contact details**  
Department of Pediatrics  
Holbaek University Hospital  
Holbaek  
Denmark  
4300

## Additional identifiers

**Protocol serial number**  
Prot-Cur 3

## Study information

### Scientific Title

Early selective treatment with Curosurf. Treatment of respiratory distress syndrome with Curosurf guided by lamellar body counts on gastric aspirate compared to treatment at arterial to alveolar oxygen tension ratio (a/APO<sub>2</sub>) <0.36. A Danish-Swedish randomised controlled study in infants at 24-29 weeks of gestation.

**Study objectives**

Early treatment with surfactant better the outcome of respiratory distress syndrome (RDS). However, only about half of preterm infants less than 30 week-gestation need surfactant when supported by early nasal continuous positive airway pressure (CPAP) or mechanical ventilation. Therefore, there is a need for a rapid and easily accessible method to predict RDS. Lamellar body counts (LBC) on gastric aspirate using automatic blood cell counters have been shown to fulfil this condition.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Research Ethics Committee of the Videnskabssetiske Committee for Bornhoms Regionskommune and Frederiksborg, Roskilde, Storstroms and Vestsjaelands Amter on 31/01/2006, (ref: Ø-2006-2-02G). All suction procedures for gastric aspirate were secure and tested. There were no serious adverse effects of Curosurf. All infants with RDS will receive Curosurf later as in our classical regiment and we have had very good results with this regiment.

**Primary study design**

Interventional

**Study design**

Phase IV international multicenter randomised controlled study

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Respiratory distress syndrome (RDS) and gestational age less than 30 weeks

**Interventions**

Randomisation to:

1. Selective treatment with Curosurf 200 mg/kg (intubation and extubation) 1-2 h after birth, guided by LBC
2. Classical Scandinavian regimen i.e. treatment with Curosurf 200 mg/kg (intubation and extubation) 5-6 h after birth when a/APO<sub>2</sub> decreases below 0.36

Trial start and end dates were amended on 24/09/09 (used to be 01/09/06 to 01/03/08). As of 28/06/2011 the end date has again been extended from 31/12/2010 to 01/08/2011.

**Intervention Type**

Drug

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Curosurf

**Primary outcome(s)**

Mechanical ventilation or death within the first 5 days of life

**Key secondary outcome(s)**

1. Mortality before discharge
2. a/APO2 after 6 days
3. Mechanical ventilation before discharge
4. Pneumothorax
5. Lung haemorrhage
6. Diastolic arterial pressure (DAP)
7. Necrotising enterocolitis (NEC)
8. Chronic lung disease (CLD) or bronchopulmonary dysplasia (BPD)
9. Intraventricular hemorrhage (IVH)
10. Periventricular leukomalacia (PVL)
11. Retinopathy of prematurity (ROP)
12. Duration of oxygen treatment (days)
13. Duration of nasal CPAP (days)
14. Duration of mechanical ventilation (days)

**Completion date**

01/08/2011

**Eligibility****Key inclusion criteria**

1. Gastric aspirate (GA) 24 + 0 to 29 + 9 weeks
2. Early nasal CPAP
3. Gastric aspirate obtained not later than 45 min after birth
4. Informed consent before birth or latest 1 h after birth

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

1. Prolonged rupture of the membranes >3 weeks
2. Therapeutic infusions in the amniotic cave
3. Lethal malformations
4. Intubation in the delivery room or before randomisation
5. Meconium or pus contamination of the gastric aspirate
6. The neonatal ward too busy with other patients
7. No gastric aspirate

**Date of first enrolment**

22/03/2007

**Date of final enrolment**

01/08/2011

## **Locations**

**Countries of recruitment**

Denmark

Sweden

**Study participating centre**

**Department of Pediatrics**

Holbaek

Denmark

4300

## **Sponsor information**

**Organisation**

Individual Sponsor (Denmark)

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Danish Medical Research Foundation for Region 3 (Denmark)

**Funder Name**

Cheisi Farmaceutici (Italy)

**Funder Name**

Nycomed (Denmark)

# Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration