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

Submission date 28/03/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/05/2006	**Overall study status** Completed	
Last Edited 28/06/2011	**Condition category** Respiratory	

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
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/APO2) <0.36. A Danish-Swedish randomised controlled study in infants at 24-29 weeks of gestation.

Study objectives
Early treatment with surfactant betters 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 Videnskabsetiske 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.

Study design
Phase IV international multicenter randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please use the contact details below to request a patient information sheet

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/APO2 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 measure
Mechanical ventilation or death within the first 5 days of life

Secondary outcome measures
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)

Overall study start date
22/03/2007

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

Age group
Neonate

Sex
Both

Target number of participants
Prior to 24/09/09: 260. Interim calculation after 130 patients Amended 24/09/09: 380. Interim calculation after 190 patients Last Patient included on 26/04/2011

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)

Sponsor details
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Sponsor type
University/education

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

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