

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

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

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