

Surfactant application during spontaneous breathing in premature infants <27 weeks

Submission date 25/02/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/03/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/06/2015	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00751959

Protocol serial number
Uni-Koeln-439

Study information

Scientific Title

Surfactant application during spontaneous breathing with continuous positive airway pressure (CPAP) or during mechanical ventilation in the therapy of infant respiratory distress syndrome (IRDS) in premature infants <27 weeks

Acronym

NINSAPP

Study objectives

This study investigates the efficacy of surfactant application during spontaneous breathing with CPAP in avoiding death and chronic lung disease (CLD) in very immature infants with a gestational age of less than 27 weeks.

On 27/03/2012, the following changes were made on the trial record:

1. The overall trial end date of trial was changed from 31/07/2011 to 31/12/2012.
2. The target number of participants has been amended from 180 to 210.

On 18/07/2012 the overall trial end date was changed from 31/12/2012 to 21/06/2012.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University of Cologne – submission pending

Primary study design

Interventional

Study design

Prospective randomised controlled multi-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mortality and chronic lung disease in very immature infants

Interventions

Experimental intervention: Surfactant application via a thin endotracheal catheter during spontaneous breathing with CPAP, followed by respiratory support with CPAP

Control intervention: Conventional therapy with intubation, initiation of mechanical ventilation and surfactant application

Intervention Type

Procedure/Surgery

Primary outcome(s)

Survival until term without CLD

Key secondary outcome(s)

The following will be followed up until 36 weeks of gestational age:

1. Survival until term without CLD, intraventricular hemorrhage (IVH) > grade II, cystic periventricular leukomalacia (PVL), retinopathy of prematurity (ROP) with need for surgery
2. Air leak syndrome (pneumothorax, pneumopericardium, pulmonary interstitial emphysema)
3. Necrotizing enterocolitis (NEC) with need for surgery
4. IVH (all grades)
5. Cystic PVL
6. ROP with need for surgery
7. Persistent ductus arteriosus (PDA) with need for surgery
8. Intubation and any mechanical ventilation during the first 96 hours
9. Days on mechanical ventilation
10. Days on nasal CPAP (nCPAP)
11. Days on supplemental oxygen
12. Duration of hospital stay
13. Daily increase in body weight

Completion date

21/06/2012

Eligibility

Key inclusion criteria

1. Gender: both
2. IRDS with Silverman-Score ≥ 5 and/or $\text{FiO}_2 \geq 0.3$
3. Postnatal age of more than 10 min and less than 2 hours
4. Gestational age $\geq 23+0$ and $<27+0$ weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Primary cardio-pulmonary resuscitation
2. Prenatally diagnosed severe malformation
3. No parental consent
4. Participation in another interventional trial

Date of first enrolment

01/08/2008

Date of final enrolment

25/03/2012

Locations

Countries of recruitment

Germany

Study participating centre

University of Cologne

Cologne

Germany

D-50937

Sponsor information

Organisation

University of Cologne (Germany)

ROR

<https://ror.org/00rcxh774>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

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	01/08/2015		Yes	No