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Surfactant application during spontaneous breathing in premature infants <27 weeks

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

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

Study design
Prospective randomised controlled multi-centre trial

Primary study design
Interventional

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 FiO2 >= 0.3
3. Postnatal age of more than 10 min and less than 2 hours
4. Gestational age >= 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 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes