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Avoid Mechanical Ventilation: The AMV-trial

Submission date
27/09/2007

Recruitment status
No longer recruiting

Registration date
15/11/2007

Overall study status
Completed

Last Edited
20/12/2011

Condition category
Neonatal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number
2006-006912-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AMV-12_12_2006 Vers. 2

Study information

Scientific Title

Acronym
AMV

Study objectives
The primary objective of this study is to demonstrate that the treatment of preterm infants with intratracheal instillation of surfactant shortly before an expected intubation is able to reduce the frequency of mechanical ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Ethikkommission der medizinischen Fakultat der Universitat Lubeck) on the 3rd July 2007 (ref: 07-037).

Study design
Prospective, interventional, randomised controlled multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory distress syndrome of preterm infants

Interventions
Please note that as of 25/08/10 the patient enrollment phase of this trial has been completed.

Intervention:
Surfactant is given at a dose of 100 mg surfactant per kg body weight via a thin gastric tube into the trachea of the spontaneously breathing infants. Surfactant without intubation will be given as a single dose at the first day of life. Repeated surfactant treatment without intubation is possible until the third day of life.

Control group:
Standard care.

Intervention Type

Drug

Phase
Not Specified

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

Primary outcome measure
The primary outcome is a combined parameter which is measured between the 25th and 72nd hour of life (day 2 and 3 of life). The primary endpoint is positive if an infant is:
1. Intubated and ventilated between the 25th and the 72nd hour of life
2. Fraction of inspired Oxygen (FiO2) is greater than 0.6 for more than two hours between the 25th and the 72nd hour of life (to keep oxygen saturation above 85%)
3. Partial pressure of Carbon Dioxide (pCO2) greater than 65 mmHg for more than two hours between the 25th and 72nd hour of life

Secondary outcome measures
1. Ventilation rate
2. Intraventricular Haemorrhage (IVH)
3. Periventricular Leukomalacia (PVL)
4. Bronchopulmonary Dysplasia (BPD)
5. Death
6. Operation due to retinopathy (Retinopathy Of Prematurity [ROP])
7. Patent Ductus Arteriosus (PDA)
8. Necrotising Enterocolitis (NEC)
9. Intestinal perforation
10. Hydrocephalus and ventricular-peritoneal-shunt
11. Number of surfactant doses
12. Total surfactant (mg/kg bodyweight)
13. Days on assisted ventilation
14. Days on supplemental oxygen
15. Duration of hospitalisation
16. Weight gain per day
17. Pneumothorax
18. Other complications of prematurity

All outcomes will be measured until discharge. Bronchopulmonary dysplasia will be assessed at 36 weeks + 0 days (+/- 5 days) of corrected gestational age.

Overall study start date
27/09/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria

1. Preterm infants with a gestational age between 26 weeks + 0 days and 28 weeks + 6 days
2. Birth weight below 1500 g
3. Age less than 12 hours

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Lethal malformations
2. Prior surfactant treatment without intubation

Date of first enrolment
27/09/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
Universitatsklinikum Schleswig-Holstein
Lubeck
Germany
D-23538

Sponsor information

Organisation
Schleswig-Holstein University Hospital (Universitatsklinikum Schleswig-Holstein) (Germany)

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
http://www.uk-sh.de/

ROR
https://ror.org/01tvm6f46

Funder(s)

Funder type
Industry

Funder Name
Chiesi Farmaceutici S.p.A. (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/11/2011		Yes	No