Avoid Mechanical Ventilation: The AMV-trial

Submission date Recruitment status Prospectively registered 27/09/2007 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 15/11/2007 Completed [X] Results [] Individual participant data Last Edited Condition category 20/12/2011 **Neonatal Diseases**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Wolfgang Gopel

Contact details

Universitatsklinikum Schleswig-Holstein Ratzeburger Allee 160 Kinderklinik Lubeck Germany D-23538 goepel@paedia.ukl.mu-luebeck.de

Additional identifiers

Clinical Trials Information System (CTIS)

2006-006912-31

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

ROR

https://ror.org/01tvm6f46

Funder(s)

Funder type

Industry

Funder Name

Chiesi Farmaceutici S.p.A. (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot 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