

Avoid Mechanical Ventilation: The AMV-trial

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 Fakultät der Universität Lubeck) on the 3rd July 2007 (ref: 07-037).

Primary study design

Interventional

Study design

Prospective, interventional, randomised controlled multicentre trial

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

Universitätsklinikum Schleswig-Holstein

Lubeck

Germany

D-23538

Sponsor information**Organisation**

Schleswig-Holstein University Hospital (Universitätsklinikum 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 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