The effect of severe respiratory syncytial virus (RSV) lower respiratory tract infections in mechanically ventilated infants younger than 12 months of age on recurrent wheezing and lung function

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Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory tract infections
Study type	Observational invasive

Summary

ID

NL-OMON34923

Source
ToetsingOnline

Brief title
RSV, mechanical ventilation and recurrent wheezing

Condition

- Respiratory tract infections

Synonym
bronchiolitis/pneumonia, RSV lower respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Beatrix Kinderziekenhuis

Intervention

Keyword: Lung function, Mechanical ventilation, Recurrent wheezing, RSV

Outcome measures

Primary outcome

- To study the occurrence of recurrent wheezing following hospitalisation for

severe RSV LRTD, and to study the differences in occurrence between ventilated

and non-ventilated infants

- To study differences in lung function testing one year after hospitalisation

for RSV LRTD between ventilated and non-ventilated infants

Secondary outcome

To study the differences in clinical, virological and immunological

characteristics in relation to recurrent wheezing following hospitalisation for

severe RSV LRTD between ventilated and non-ventilated infants.

Study description

Background summary

Respiratory syncytial virus (RSV) is the predominant pathogen of lower respiratory tract disease (LRTD) in infants. In the Netherlands ± 5000 infants are annually admitted to hospital due to RSV related LRTD, approximately 2% - 16% needs to be mechanically ventilated. Treatment for these infants is supportive; corticosteroids and bronchodilators are not beneficial (3). RSV LRTD leads to serious respiratory sequelae with ± 50% of hospitalised patients suffering from recurrent wheezing resembling childhood asthma persisting until early school age. significant proportion of patients with recurrent wheezing

receive asthma medications and experience decreased health-related quality of life. Furthermore, hospitalized infants have impaired lung function during follow-up compared to healthy controls. We hypothesize that recurrent wheezing after severe RSV LRTD occurs significantly more often in ventilated than in non-ventilated infants. This is explained by a higher viral load, a more dampened T * cell response and more lung injury (defined by circulating biomarkers) in ventilated infants. One year after severe RSV LRTD, airway resistance is significantly higher in ventilated infants than in non-ventilated infants.

Study objective

The primary objective is a) to study the occurrence of recurrent wheezing following hospitalisation for severe RSV LRTD, and to study the differences in occurrence between ventilated and non-ventilated infants, and) to study differences in lung function testing one year after hospitalisation for RSV LRTD between ventilated and non-ventilated infants. Secondary objectives are to study the differences in clinical, virological and immunological characteristics in relation to recurrent wheezing following hospitalisation for severe RSV LRTD between ventilated and non-ventilated infants.

Study design

This is a prospective, longitudinal cohort-study of patients admitted with RSV lower respiratory tract infection to the Beatrix Children*s Hospital/University Medical Center Groningen comprising four consecutive RSV seasons (October to March) between 2010 and 2014.

Study burden and risks

Measurements will be performed in all infants on day 1, 3 and 5 of admission including blood sampling (2 ml per sampling) through a venous puncture in non-ventilated infants, and obtaining nasopharyngeal aspirates. In ventilated infants measurements will also be performed on day 1, 3 and 5 of admission including blood sampling (2 ml per sampling) using the indwelling arterial line, obtaining nasopharyngeal aspirates and obtaining broncho-alveolar lavage fluids. Regional lung filling characteristics will be measured using electrical impedance tomography (EIT). During the first year of follow-up parents or legal care-takers of all included infants are asked to daily fill out a patient diary, recording respiratory symptoms including cough, rhinitis, wheezing, and consultation of a physician and use of bronchodilators. One year after discharge, lung function testing including FRC and airway resistance will be performed with the whole-body plethysmography in all included infants.
The risks associated with this project are considered minimal: ventilated infants who undergo a broncho-alveolar lavage may experience a brief period of a decrease in transcuteaneously measured oxygen saturation. Obtaining a

nasopharyngeal aspirate in infants does not cause any extra risk, but may be experienced is uncomfortable for a brief period in non-ventilated infants. Blood sampling is done using the indwelling arterial catheter in ventilated infants; however in non-ventilated infants a venous puncture has to be performed. Lung function testing one year after discharge requires the infant to be mildly sedated using oral chloralhydrate; because of this a physician trainined in advanced paediatric life support will be present during this procdure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Age < 12 months
- Admitted with a first episode of RSV LRTD as defined with one or more of the following signs and symptoms: body temperature * 37.5° C, cough, rhinitis, wheezing on pulmonary

auscultation, and crackles on pulmonary auscultation
-Virogically confirmed RSV LRTD (i.e. a positive direct immunofluorescent assay (DIFA) or a positive RSV-enzyme immunoassay (EIA)

Exclusion criteria

- Age * 12 months
- Infants born after a gestation * 32 weeks
- Infants with chronic lung disease of prematurity (defined by oxygen dependency between 28 and 56 days after birth)
- Infants with a haemodynamically significant congenital heart disorder
- Infants with an immunodeficiency
- Infants with a congenital or acquired neuromuscular disorder
- Infants managed only in the outpatient department
- Infants with a nosocomial (i.e. hospital acquired) RSV LRTD

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Ethics review

Not approved

Date:	22-07-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31181.042.09