Pulmonary function after mechanical ventilation for respiratory syncytial virus induced respiratory failure in infancy

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Primary Objective: *To study differences in pulmonary function (i.e. increased airway resistance) one year after hospitalisation for RSV LRTD between mechanically ventilated and non-ventilated infantsSecondary Objectives: *To study...

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

Summary

ID

NL-OMON36654

Source
ToetsingOnline

Brief title
RSV, mechanical ventilation and lung function

Condition

- Respiratory tract infections

Synonym
bronchiolitis/pneumonia, Respiratory syncytial virus lower respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting Beatrix Kinderziekenhuis;Fonds NuthsOhra zorgsubsidie

Intervention

Keyword: Lung function, Mechanical ventilation, RSV

Outcome measures

Primary outcome

Differences in pulmonary function (i.e. airway resistance), one year after hospitalisation for RSV LRTD between mechanically ventilated and non-ventilated infants

Secondary outcome

*Differences in and time course of clinical, virological and immunological characteristics and markers for lung injury between mechanically ventilated and non-ventilated infants

*Differences in frequency of recurrent wheezing during the first year following hospitalisation for RSV LRTD between mechanically ventilated infants and non-ventilated infants. Recurrent wheezing is defined by at least one episode of parental reported wheezing (i.e. two or more consecutive days with wheeze)

*The frequency of recurrent wheezing in relation to impaired pulmonary function (i.e. airway resistance)

Study description

Background summary

It is well established that the maximal level of pulmonary function reached after puberty is a crucial determinant of the risk for chronic obstructive pulmonary disease (COPD) in later life. COPD is defined by an FEV1/FVC ratio of less than 70%, and thus subjects who start adult life with lower ratios will attain this threshold much earlier. This irrefutably implies that any injury to the developing paediatric lung will have a negative effect. Respiratory

syncytial virus (RSV) is the predominant pathogen of lower respiratory tract disease (LRTD) in infants that can only be supportively managed. A significant proportion of young infants hospitalised with RSV LRTD need to be mechanically ventilated. Although life-saving for these infants, mechanical ventilation also aggravates pre-existing lung injury yielding additional detrimental effects on patients outcome (double-hit principle). Therapeutic modalities such anti-inflammatory drugs (for instance corticosteroids) lack any benefit. This is mainly due to the fact that the underlying pathophysiological mechanisms are far from elucidated. This research project therefore is designed to study the effects of RSV LRTD in mechanically ventilated infants on pulmonary function during follow-up, as well as potential underlying pathophysiological mechanisms so that ultimately therapeutic modalities can be developed that prevent a decrease in lung function.

Study objective

Primary Objective:
*To study differences in pulmonary function (i.e. increased airway resistance) one year after hospitalisation for RSV LRTD between mechanically ventilated and non-ventilated infants

Secondary Objectives:
*To study pathophysiological mechanisms contributing to impaired pulmonary function (i.e. increased airway resistance) including clinical, virological and immunological characteristics, level and time course of mechanical ventilation, and presence of lung injury as defined by circulating biomarkers
*To study the difference in frequency of recurrent wheezing during the first year following hospitalisation for RSV LRTD between mechanically ventilated and non-ventilated infants
*To study the frequency of recurrent wheezing in relation to impaired pulmonary function (i.e. increased airway resistance)

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 October 1, 2011 and March 31, 2015.

Intervention

Not applicable

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 or using the indwelling arterial line in ventilated infants, nasopharyngeal aspirates in all infants and broncho-alveolar lavage fluids in ventilated infants. 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 moderate: ventilated infants who undergo a broncho-alveolar lavage may experience a brief period of a decrease in transcutaneously measured oxygen saturation. Obtaining a nasopharyngeal aspirate in infants does not cause any extra risk, but may be experienced as 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 that is very often used for procedural sedation in children; nevertheless, because of this a physician trained in advanced paediatric life support will be present during this procedure.

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))
*For group III: post-operative admittance after elective surgery

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:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120
Type:	Actual

Ethics review

Not approved

Date:	19-09-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL34681.000.10