Ventilator induced lung injury by mechanical ventilation in children with respiratory syncytial virus infection.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Observational invasive

Summary

ID

NL-OMON36852

Source
ToetsingOnline

Brief title
VILI-RSV

Condition

- Respiratory tract infections

Synonym
bronchiolitis, Respiratory syncytial virus infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Catharijne Stichting

Intervention

Keyword: Mechanical Ventilation (MV), Respiratory Syncytial Virus (RSV), Ventilator Induced Lung Injury (VILI)

Outcome measures

Primary outcome

An undiluted nasopharyngeal aspirate (NPA) will be taken within 1 hour before intubation followed by an endotracheal aspirate (ETA) at 6, 24 and 48 hours after intubation. In non-intubated patients a NPA will be taken at 0, 6, 24 and 48 hours after the first NPA. Cytokine concentrations in NPA /ETA will be determined; IL-1, IL-6, TNF-*, IL-10 and IL-8 will be measured using the Luminex fluorescent-bead-based technology. Of the ventilated patients, 2 ml blood will be collected every 48 hours for immunological studies.

Secondary outcome

Not applicable

Study description

Background summary

Respiratory Syncytial Virus (RSV) lower respiratory tract infection (LRTI) is the most frequent cause of Pediatric Intensive Care Unit (PICU) admission for mechanical ventilatory support in infants during the winter season. Life-saving mechanical ventilation (MV) however may induce or aggravate pulmonary inflammation and lung injury. When pulmonary inflammation is already present when MV is applied, this inflammation is probably enhanced. Therefore, it is reasonable to assume that MV will profoundly modulate RSV induced inflammation. Currently, the role of ventilation-induced lung injury (VILI) is studied by the applicants in a mouse model. The aim of the proposed study is to translate the same hypothesis to humans: mechanical ventilation aggravates RSV-induced airway inflammation.

Study objective

The aim of this study is to compare the time course of cytokines (markers for inflammation) in the following 3 groups: RSV-positive, ventilated patients; RSV-positive, non-ventilated patients and RSV-negative, ventilated patients. The main hypothesis is that MV aggravates RSV-induced airway inflammation as determined by repeated measurement of local cytokine concentrations.

Study design

The pilot study will be an observational multi-center, prospective, case control study.

Study burden and risks

From each patient a maximum of 4 samples [aspirates] will be obtained.
Burden:
* Nasopharyngeal aspiration is a non-invasive technique where mucus is suctioned from the nose. The burden for the patient is low, consisting of discomfort during less than 10 seconds. Most children admitted to the hospital for respiratory illness during the winter season undergo this diagnostic procedure to determine if they are RSV positive or negative. Also due to obstruction of the nose by mucus the nose will be suctioned frequently in LRTI patients. Medical staff is experienced with this technique. No complications have been described.
* Endotracheal aspiration is a non-invasive technique where mucus is suctioned from the endotracheal tube. The burden for the patient is low and all children requiring mechanical ventilation, regardless of the reason for their respiratory insufficiency, undergo this procedure routinely several times per day to prevent endotracheal tube obstruction and subsequent ventilator problems. Endotracheal suctioning is also used for several diagnostic procedures and poses little risk. No complications have been described.
* Bloodsampling: Every 48 hours 2 ml blood is taken from a central venous, arterial catheter or during peripheral venous cannulation during anesthesia for cellular immunological studies. This amount has been considered safe by the WKZ/UMCU METC in our previous studies in a population with identical inclusion criteria.

Possible benefit:
There is no clear clinical benefit for the infants participating in this proposed study.
* Nasopharyngeal aspiration: the sample before intubation is necessary to clear the upper airways (infants obligatory breathe through the nose). Subsequent NPA samples have no possible benefit.
* Endotracheal aspiration: preventing tube obstruction and therefore avoiding ventilator problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Index group (n<=25):
* Age < 13 months
* Strong suspicion or proven RSV LRTI (positive PCR or DIFF)
* Respiratory insufficiency requiring mechanical ventilation
Ventilated control group (n<=25):
* Age < 13 months
* Mechanical ventilation for elective surgery (e.g. diagnostic cardiac catheterisation, hernia inguinalis correction)
Non-ventilated control group (n<=25):
* Age < 13 months
* Proven RSV LRTI
* Hospitalisation due to RSV LRTI (e.g. for oxygen suppletion, nasal gastric tube feeding)

Exclusion criteria

* Previous airway morbidity in all groups
* Severe co-morbidity (p.e. congenital heart disease, prematurity <33 weeks) in the index group
* Current signs of airway infection (runny nose) in the ventilated control group
* Cardiac surgery less than 3 months before elective diagnostic cardiac catheterisation or cyanotic cardic disease in the ventilated control group.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2009
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	11-03-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-10-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-08-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-03-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL25193.098.08