RRR Study: study on the role of inhibitory receptors in respiratory syncytial virus (RSV) bronchiolitis

Published: 29-04-2011
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To determine the expression of inhibitory receptors on immune competent cells in patients and healthy controls

Ethical review	Approved WMO
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON34523

Source
ToetsingOnline

Brief title
RRR Study

Condition

- Viral infectious disorders

Synonym
bronchiolitis, luchtwegontsteking

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bronchiolitis, inhibitory receptor, respiratory syncytial virus

Outcome measures

Primary outcome

Main study parameters/endpoints: (1) expression of inhibitory receptors in peripheral blood and tracheal aspirate, (2) concentration of soluble inhibitory receptors in plasma, nasopharyngeal aspirates and urine.

Secondary outcome

A secondary objective is to study changes in bacterial carriership during the course of infection, which will be studied in nasopharyngeal swabs on admission and 1 month later.

Study description

Background summary

Respiratory syncytial virus bronchiolitis is the most frequent cause of hospitalization during infancy. The pathogenesis is not well understood. No effective treatment is available. In literature, is has been suggested that disease is the consequence of lack of immune regulation. The hypothesis tested in this study is that RSV bronchiolitis is associated with expression of inhibitory receptors.

Study objective

To determine the expression of inhibitory receptors on immune competent cells in patients and healthy controls

Study design

Observational case-cohort study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
A single venapuncture will be taken, which is unlikely to be part of normal care. Drawing venous blood is moderately painful.
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. For children from control population who are not ventilated and without LRTI, nasopharyngeal aspiration is not required for patients not participating in this study.
Nasopharyngeal swab is a non-invasive technique where mucus is swabbed from the nose. The burden for the patient is even lower than nasopharyngeal aspiration, because the duration is less than 10 seconds and the the swab is very soft. Medical staff is experienced with this technique. No complications have been described.
Urine will be collected by a simple bag. This can be used in both boys and girls. Urine collection is associated with low burden for the patient.
Tracheal aspirate in ventilated RSV patients and ventilated controls will only be taken as part of routine care
Possible benefit:
There is no clear clinical benefit for the infants participating in this proposed study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children under the age of 13 months that require mechanical ventilation for symptoms of respiratory syncytial virus (RSV) lower respiratory infection, known as the index group. In addition, 3 control populations will included: hospitalized RSV patients who do not require mechanical ventilation, ventilated control patients without infection and non-ventilated control patients without infection

Exclusion criteria

Severe comorbidity, such as any organ dysfunction
Any Syndromal abnormality, such as Down Syndrome
Any other infection during past 14 days

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO Date:	29-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL33225.041.10