Diagnosis of respiratory tract infections by molecular techniques in pediatric patients

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Goal of this study is to obtain more insight into causative agents of respiratory tract infections in children using molecular techniques and how results of molecular test should be interpretated in relation to clinical symptoms. The optimal...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON32220

Source
ToetsingOnline

Brief title
REMODEL

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Respiratory tract infections

Synonym
Respiratory tract infection

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, PCR, respiratory infections, respiratory pathogens

Outcome measures

Primary outcome

1) The detection of different pathogens in correlation to clinical symptoms.

2) Comparison of the pathogen load between different clinical patherns.

Secondary outcome

1) What is the difference in detection of the same pathogen, with different

sampling methods

2) How long does pathogen DNA or RNA remain detectable during the course of

disease in a hospitalized patient?

Study description

Background summary

Acute respiratory infections are one of the most important reasons for hospitalisation of young children. This is not only an important cause of morbidity for patients, but it also causes substantial health care expenses due to hospitalisation, diagnostic procedures and therapy.
In a lot of cases a causing pathogen is not found, due to lack of sensitivity of culture and serology or lack of adequate samples for diagnostic testing. This may result in suboptimal treatment and longer hospitalisation. More sensitive and rapid testing is needed to increase pathogen detection rates so adequate treatment can be given.

Study objective

Goal of this study is to obtain more insight into causative agents of respiratory tract infections in children using molecular techniques and how results of molecular test should be interpretated in relation to clinical symptoms. The optimal clinical material for molecular testing will be assessed as well.

Key questions are:
- What is the frequency of the different pathogens when molecular test are used.
- Are there associations with clinical features?
- What is the best way of sampling for molecular tests?
- Is there a correlation between the amount (= load) of a pathogen and the clinical picture.
- What is the meaning of multiple postive test, for different pathogens, with this sensitive test.
- How long can DNA/RNA be detected after the onset of symptoms, with and without treatment.

Study design

This study will be carried out in two different hospitals.
Parents of children suspected of respirator tract infection will be asked to participate in the study. After informed consent, different respiratory tract materials will be obtained (nasopharyngeal wash, nasopharyngeal swab, pharynx swab and a urine sample). If blood is drawn from a patient for routine diagnostic purpose, an additional 2 ml will be taken to test for (invasive) respiratory pathogens. If patients are still in the hospital on day 3 and 7, nasopharyngeal wash, nasopharyngeal swab and pharynx swab will be repeated. Nurses specialised in children care will perform the sampling procedures. The treating physician shall ask for informed consent and will fill in the case record form. The principle investigator will visit the wards and help when there are questions or difficulties.
Results will be correlated to clinical symptoms. Sample methods will be compared with each other.
This study will last 2 years to include a total of 300 patients.

Study burden and risks

The nature and extent of the burden exists of:

1) An unpleasant sensation during the sampling of nasopharyngeal samples.
2) Urine sampling with urine bag sticked to skin can give some irritation during removel, comparble with the removel a plaster.

If a diagnosis of an atypical bacteria or virus is confirmed antibiotics can by revised or stopped. This will be beneficial to the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

All children admitted at the Emma Children's or Amstelland hospital with suspected respiratory tract infection.

Exclusion criteria

Age of 18 years or older.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL20229.018.07