Diagnosis of respiratory tract infections by molecular techniques in pediatric patients: Significance of positive samples with this ultra sensitive technique and analysis of the best sampeling method

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Ethical review	-
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON32174

Source
ToetsingOnline

Brief title
MODEL Study

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) Comparison of the sensitivity between different way's of sampeling for

patient materials?

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

Secondary outcome

1) What is the role of co-pathogens?

2) How long can DNA be shown (by a positive test) , during the course of

disease, in 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 a cause for morbidity and mortality of the individual, but can also be a reason for healthcare cost 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, and because sputum can not always be obtained. 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

The objective of the study is to get more insight into the interpretation of

multiplex PCR test (which are so sensitive, that falls positive samples due to colonisation, or interpretation problems due to mixed infection may occur) and to expand a real-time multiplex pcr assay from 14 to 20 different pathogens, for fast and ultra sensitive detection of most important respiratory bacteria and viruses. These pathogens are: adeno-, influenza A en B, entero, hMP-, RS-, rhino-, corona-, parecho- en parainfluenza- 1,2,3,4, boca- virus, Streptococcus pneumnoniae, Mycoplasma pneumoniae, Chlamydophila pneumoniae, Chlamydophila psitacci, Legionella pneumophila en Bordetella pertussis en parapertussis.

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 with respiratory complaints (indoor and outdoor patients) will be asked to participate in the study. After informed consent, 5 materials will be taken from the patient: 1) nasopharyngeal wash, nasopharyngeal swab, pharynx swab, a urine sample and 5ml of venous blood. If patients are still in the hospital on day 3 and 7, nasopharyngeal wash, nasopharyngeal swab and pharynx swab will be taken for a second and third time. Nurses specialised in children care will perform the sampling procedures. The treating physician shall ask for informed consent and has to fill in the case record form. The head investigator will visit the wards and help when there are questions or difficulties.
All data will be stored anonymously in a database and will be analysed later.Analysed PCR results will be compared with the full spectrum of routine techniques. Sample methods will be compared with each other.
This study will have a total duration of 2 years to include 300 patients

Study burden and risks

The nature and extent of the burden will exist of:

1) An unpleasant sensation during the sampling of nasopharyngeal samples.
2) The pharynx sample may also give a heave reflex.
3) Urine sampling with urine bag sticked to skin can give some irritation

during removel, comparble with the removel a plaster.
4) Venous puncture gives a painful sensation during the insertion of the needle and can lead to a haematoma.

If a patient is still hospitalised on day 3 and 7 he will, this burden will be increased with two extra episodes of nasopharyngeal and pharynx samplimg. The total time of burden will maximally be 3x7 = 21 minutes, plus 20 minutes of explanation
Besides these significant, but reversible and short lasting burdens, this study does not impose a real risk on the partcipating patients.

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

1) All children admitted at the Emma Children's or Amstelland hospital with presumed respiratory tract infection.
2) All children who present at the outdoor clinic of the Emma Children's or Amstelland hospital with presumed 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:	Will not start
Start date (anticipated):	01-10-2007
Enrollment:	300
Type:	Anticipated

Ethics review

Not available

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	NL19700.018.07