INTRODUCTION OF VIRAL PCR DIAGNOSTICS IN PEDIATRIC RESPIRATORY TRACT INFECTION: EFFECS ON TREATMENT AND COSTS

Published: 31-10-2006
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Impact of introduction of real-time viral PCR on clinical decision making and costs in children with a respiratory tract infection.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON31503

Source
ToetsingOnline

Brief title
VIDERO - trial

Condition

- Respiratory tract infections

Synonym
respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Financiering door ZonMW is afgewezen.

Deels financiering materialen door wetenschappelijke activiteitencommissie Reinier de Graaf Groep

Intervention

Keyword: children, real-time PCR, respiratory tract infections, viral

Outcome measures

Primary outcome

Costs of viral PCR diagnostics. Cost changes as a result of introduction of PCR

diagnostics. Changes in clinical decision making: duration of hospital stay,

outpatient clinic visits, use of antibiotics, other medication. Use of the

viral PCR in daily clinical practice.

Secondary outcome

Epidemiology of respiratory tract infections in children. New viral pathogens.

Relation between viruses and laboratory parameters (CRP for example)

Study description

Background summary

Respiratory infections are encountered frequently in children. They account for nearly 10% of the emergency visits and 20% of all pediatric hospital admissions. The majority is of viral origin. At least 12 different virusses are known to cause respiratory infection in children. All these virusses can be detected with PCR techniques. The PCR results can be generated within 48 hours, thereby
potentially influencing the treatment strategy. By introducing these techniques, diagnostic costs may increase tremendously. Whether these diagnsotic PCR-results are essential in clinical decision making is questionable. In respiratory infection the role of the micro-organism is overestimated. Other patient characteristics are important to tailor individual treatment.

Study objective

Impact of introduction of real-time viral PCR on clinical decision making and costs in children with a respiratory tract infection.

Study design

Randomized Clinical Trial
A cohort of 600 children is recruited in a peripheral teaching hospital (Reinier de Graaf Groep, Delft) and an university hospital (ErasmusMC - Sophia) during the first 2 years of the study. Clinical data are collected at entry of the study by case record forms. The children will be randomized in 2 arms. Treating physicians in arm A will receive the information of the PCR diagnostics within 48 hours. Treating physicians in arm B will receive the information of the PCR diagnostics after 4 weeks.
The 2 cohorts may reveal differences between the population in a peripheral teaching hospital versus the patient population of the university hospital.

Intervention

Treating physicians in arm A will receive the information of the PCR diagnostics within 48 hours

Study burden and risks

Several minutes of time will be asked at parents for gaining extra information of the clinical history of their child.
There are no risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children under age of 2 months with a respiratory tract infection
Children older than 2 months with a respiratory tract infection and severe respiratory problems with tachypnea, dyspnea or cyanosis

Exclusion criteria

Age older than 12 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006

Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2006
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-02-2009
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	NL13839.098.06