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Evaluation of Viral Diagnostics on rEspiratory iNfections in ChildrEn

Submission date	Recruitment status	[_] Prospectively registered
15/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/01/2012	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CCMO: NL13839.098.06

Study information

Scientific Title
Evaluation of viral diagnostics on respiratory infections in children: a multicentre randomised controlled trial

Acronym
EVIDENCE Trial

Study objectives
Introduction of real time polymer chain reaction (PCR) of 16 viruses and 2 bacteria for acute respiratory tract infections in children will not lead to major changes in clinical management and outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Medical Ethics Committee (METC Zuidwest Holland [Voorburg]) approved on the 31st October 2006 (ref: METC-nr 06-067)

Primary study design
Interventional

Study design
Multicentre randomised controlled trial with blind allocation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute respiratory infections

Interventions
In the intervention group, results of real-time PCR were communicated to the clinician within 48 hours. In the control group the same was provided, but after 4 weeks. Follow up time ended at discharge from the hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Changes in clinical decision making:
1. Hospital admission yes or no: measured at first clinical presentation
2. Duration of hospital stay in days: measured after discharge at hospital
3. Start of antibiotics yes or no: measured at any time from first presentation until discharge
4. Duration of antibiotic use in days when initiated: measured after discharge

Key secondary outcome(s)
Epidemiology of respiratory tract infections in children; all measured at any time from first presentation until discharge:
1. Clinical symptoms and disease severity of new viral pathogens; are there differences between the pathogens?

2. Clinical symptoms and disease severity of multiple infections; differences with monoinfections
3. Relation between viruses and laboratory parameters (C-reactive protein [CRP] for example)
4. What is the role of Bordetella pertussis in children with acute respiratory infection and should it be tested routinely
5. Cost changes as a result of introduction of PCR diagnostics

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Children under age of 2 months with a respiratory tract infection
2. Children older than 2 months with a respiratory tract infection and severe respiratory problems with tachypnoea, dyspnoea or cyanosis
3. Gender: both male and female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
2 Months

Sex
All

Key exclusion criteria
Aged older than 12 years

Date of first enrolment
01/11/2007

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Netherlands

Study participating centre

Department of Pediatrics
Delft
Netherlands
2600GA

Sponsor information

Organisation
Reinier de Graaf Hospital (Netherlands)

ROR
https://ror.org/00wkhef66

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Reinier de Graaf Hospital (Netherlands) - Research Activity Committee (WAC) (ref: 620604)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No