

# Evaluation of Viral Diagnostics on rEspiratory iNfections in ChildrEn

<b>Submission date</b> 15/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/01/2012	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**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)

**Study design**

Multicentre randomised controlled trial with blind allocation

**Primary study design**

Interventional

**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 mono-infections
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?
<a href="#">Results article</a>	results	01/11/2011		Yes	No