

Evaluation of Viral Diagnostics on rEspiratory iNfections in ChildrEn

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2007

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

Age group

Child

Upper age limit

2 Months

Sex

Both

Target number of participants

600

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)

Sponsor details

PO Box 5011

Delft

Netherlands

2600 GA

Sponsor type

Hospital/treatment centre

Website

<http://www.rdgg.nl>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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