Enterovirus- and parechovirus infection in children.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20807

Source
Nationaal Trial Register

Health condition

Enterovirus (EV), a picornavirus, is a common cause of infection in children. The incidence of EV infection in Dutch children is not exactly known. There is no official registration. EVs cause a broad range of clinical syndromes from gastro-enteritis to meningitis. The clinical presentation changes between the several subtypes. Human Parechovirus (HPeV), also a member of the Picornaviridae, is recently identified, and is associated with similar symptoms as EV infection. EV and HPeV can be diagnosed with viral cultures, reverse transcription polymerase chain reaction (PCR) of feces, urine, throat swab, blood or cerebrospinal fluid (CSF) or with serology. Not much is known about the prognosis of enterovirus and parechovirus menignitis in children.

Sponsors and support

Primary sponsor: This study was started in the St. Elisabeth Hospital Tilburg, the Netherlands, Pediatrics, C. Obihara.

There are no sponsors or fundings.
Source(s) of monetary or material Support: No fundings.

Intervention

Outcome measures

Primary outcome

1. Specific clinical symptoms in patients with proven EV or HPeV infection;

2. Different laboratory diagnostic methods: viral culture, PCR and serology;

3. Several body fluids: feces, urine, throat swab, blood, and eventually CSF;

4. Developmental milestones of children after an EV/HPeV CNS infection.

Secondary outcome

1. Morbidity due to EV/HPeV infection (hospitalization, duration of hospitalization, duration and severity of symptoms, average school- and work absence, duration use of antibiotics);

2. Antibiotic treatment of patients (antibiotics, stop of antibiotics after diagnosis of EV or HPeV infection).

Study description

Background summary

Patients are included only in the Netherlands (St. Elisabeth hospital Tilburg, Tweesteden hospital Tilburg, Amphia Hospital Breda).

Background of the study:

Enterovirus (EV), a picornavirus, is a common cause of infection in children. The incidence of EV infection in Dutch children is not exactly known. There is no official registration. EVs cause a broad range of clinical syndromes from gastro-enteritis to meningitis. The clinical presentation changes between the several subtypes. Human Parechovirus (HPeV), also a member of the Picornaviridae, is recently identified, and is associated with similar symptoms as EV infection. EV and HPeV can be diagnosed with viral cultures, reverse transcription polymerase chain reaction (PCR) of feces, urine, throat swab, blood or cerebrospinal fluid (CSF) or with serology.

Hypotheses:

(1) EVs are one of the most important viral agents of infection in Dutch children;

(2) EVs are the major cause of meningitis in Dutch children;

(3) PCR is more sensitive than viral culture and serology in the detection of EV and HPeV infection in children;

(4) HPeV is a major cause of serious infection in younger children (≤2 year) with psychomotoric and cognitive develop deficiencies.

Objective of the study:

Primary objectives:

(1) To describe the incidence of EV and HPeV infections in Dutch children;

(2) To determine the major symptoms of EV/HPeV infections in children;

(3) To evaluate the epidemiology and symptoms of the different subtypes of EV and HPeV;

(4) To compare the sensitivity and specificity of different laboratory techniques to detect EV or HPeV during infection: viral culture, PCR and serology;

(5) To determine the sensitivity and specificity of the different body fluids in diagnosis of EV or HPeV infection: feces, urine, throat swab, blood, CSF;

(6) To determine the sequelae after an EV/HPeV central nervous system (CNS) infection till 5 years after infection.

Secundary objectives:

(1) To describe the morbidity of EV and HPeV infection (hospitalization, duration of hospitalization, duration and severity of symptoms, average school- and work absence, duration use of antibiotics);

(2) To evaluate the use of antibiotics before and after the diagnosis.

Study design:

Observational multicenter study with nested case-control follow-up study. To identify EV or HPeV infection we will examine feces, urine, throat swab, blood and CSF.

The definition of cases and controle in the follow-up study is as follows:

Cases: Children with an CNS infection with EN/HPeV, proven with EV/HPeV in liquor (meningitis or encephalitis).

Control group 1: No EV/HPeV meningitis, however EV/HPeV positivity in feces, urine, throat swab or blood.

Control group 2: No EV/HPeV or other viral (or bacterial) infection proven Approximately 2 weeks after the infection, the patient will be invited for check-up for a standardized questionnaire, physical examination and for the second vena puncture. The further follow-up will consist of taking standardized questionnaires and developmental and cognitive tests at 6, 12, 24 and 60 months after the infection.

Study population:

Children ≤ 16 years of age with suspected EV or HPeV infection.

Primary study parameters/outcome of the study:

1. Specific clinical symptoms in patients with proven EV or HPeV infection;

2. Different laboratory diagnostic methods: viral culture, PCR and serology;

3. Several body fluids: feces, urine, throat swab, blood, and eventually CSF;

4. Developmental milestones of children after an EV/HPeV CNS infection.

Secundary study parameters/outcome of the study (if applicable):

1. Morbidity due to EV/HPeV infection (hospitalization, duration of hospitalization, duration and severity of symptoms, average school- and work absence, duration use of antibiotics);

2. Antibiotic treatment of patients (antibiotics, stop of antibiotics after diagnosis of EV or HPeV infection).

Study objective

To determine the epidemiology, diagnosis and prognosis of enterovirus (EV) and parechovirus (HPeV) infection in Dutch children.

Hypotheses:

1. EVs are one of the most important viral agents of infection in Dutch children;

2. EVs are the major cause of meningitis in Dutch children;

3. PCR is more sensitive than viral culture and serology in the detection of EV and HPeV infection in children;

4. HPeV is a major cause of serious infection in younger children (≤2 year) with psychomotoric and cognitive develop deficiencies.

Study design

4 follow up visits at 6, 12, 24 and 60 months after infection for standardized questionnaire, physical examination and developmental tests.

Psychotherapist: m-ABC, BSID-II.

Psychologist: BSID, CBCL, RAKIT/WPSII.

Intervention

When children are participating in the study the following materials are collected:

1. Feces;

2. Urine;

3. Nasopharynx swab;

4. Blood sample (if parents agree);

5. Cerebrospinal fluid, ONLY if the pediatrician has a suspision of a meningitis and the pediatrician says a spinal punction is indicated.

For the follow up patients are classified in one of the following groups:

1. Group 1: Children with an EV or HPeV menignitis;

2. Group 2: Children with an EV or HPeV infection but no meningitis;

3. Group 3: Children suspected for an EV or HPeV infection, but there was no proven cause of infection (no EV, HPeV or other virus/bacteria was found).

For the follow up patients are seen in our outpatient clinic 2 weeks after the infection by the pediatrician. Furthermore there are 4 follow up visits at 6, 12, 24 and 60 months after infection for standardized questionnaire, physical examination and developmental tests (m-ABC/ BSID-II). They are seen by the pediatrician, psychoterapist and psychologist.

Contacts

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Eligibility criteria

Inclusion criteria

A + B are required.

A. All Children ≤ 16 years of age with a clinical suspicion of an EV/HPeV infection:

1. Fever (temperature ≥38,0 degrees C) OR;

2. Meningeal inflammation: (Anamnestic or with examination at least 2 of the following: headache, photophobia, nuchal rigidity, irritability, lethargy, nausea, vomiting, drowsiness,

positive sign of Kernig or Brudzinsky) OR;

3. At least 3 of the following: Hypothermia, headache, drowsiness, nuchal rigidity, irritability, photofobia, vomiting, diarrhea, anorexia, couhing, myalgia, rash OR;

4. Sepsis: Clinical suspicion of an infection plus: - temperature >38,5 degrees C of < 36 degrees C rectal or oral - tachycardia: heart rate > 2 SD for age OR children < 1 year with a bradycardia: heart rate < 2 SD for age - tachypnea: breathing rate> 2 SD for age.

B. Signed informed consent by the parent(s)/legal guardian(s).

Exclusion criteria

1. Other proven cause of the infection: Positive bacterial, viral (other than EV/HPeV), parasitic or fungal/yeast culture or PCR (feces, urine, throat swab, blood, CSF);

2. Other causes of illness: Neoplasma, auto-immune diseases, rheumatic diseases, endocrinologic diseases, gastrooesophageal reflux, etcetera;

3. Known psycho-motor retardation, metabolic diseases with neuro-muscular or cognitive abnormalities;

4. Patients older than 16 years of age;

5. No signed informed consent from the parent(s)/ legal Guardian(s).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-03-2008

Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion
Date: 12-12-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31728
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3045
NTR-old	NTR3193
CCMO	NL21361.008.07
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON31728

Study results

Summary results
N/A