Trial Description

Title

Liver involvement during acute respiratory tract infection in children and adolescents

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In children and adolescents hospitalized due to acute respiratory tract infections elevation of liver enzymes is a frequent observation. According to the literature viruses causing respiratory infections are not always constricted to the respiratory tract; they can reach the circulation and also the liver which can lead to hepatic infection. Isolation of certain viruses or its genetic material from the liver has been reported, too. With our study we want to discover the frequency of liver involvement in children with respiratory infections and identify viruses which are mainly responsible for it.

Brief Summary in Scientific Language

Title:
Liver involvement during acute respiratory tract infection in children and adolescents

Objectives:
1. Detection of the frequency of liver involvement during acute respiratory tract infections in children.
2. Which viruses are mainly responsible for the respiratory infections?
3. Which viruses may cause hepatic infection?

First patient in: January 2014
Study duration: 2-3 years
Study duration for patients: 3-7 days

Methods:
Monocentric observational study including up to 1,000 pediatric patients aged between 1 and 18 years who are hospitalized for uncomplicated acute upper or lower respiratory tract infection; outpatients can be included, too. Besides standard diagnostics quantification of liver enzymes (ASAT, ALAT, Gamma-GT, alkaline phosphatase, bilirubin (total, direct and indirect) and albumin) is performed. Blood samples are taken two times, each time an approximate amount of 3 mL for study purposes only: for hospitalized patients at clinical admission and at discharge, and for outpatients at study entry and 3-7 days later; thus, outpatients will be asked to visit the clinic again for the second blood sampling. Additionally, every patient receives a nasal lavage with physiologic salt solution

(NaCl) within 24 hours after study entry for detection of viral pathogens by means of PCR (Polymerase-Chain-Reaction). Patients will be interviewed about further potential reasons for elevated liver enzymes; these reasons and the medication taken during the last 30 days as well as during the study period will be documented.
Patients who show an at least two-fold increase of liver enzymes at the time of the second blood sampling will be examined again after 7-10 days (including a third blood sampling). If elevation of liver enzymes still persists (two-fold increase or more) further diagnostics will be performed. Every medication administered during the study period is for treatment of the acute respiratory infection. No medication will be given for study purposes. Statistical analysis is explorative and focuses on incidences of liver involvement in the study population and in specific virus-related subgroups.

Organizational Data

- DRKS-ID: **DRKS00005592**
- Date of Registration in DRKS: **2014/01/09**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2013-528-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- Free text: **acute respiratory tract infections**
- Free text: **hepatic infection**
- ICD10: **J00-J06 - Acute upper respiratory infections**
- ICD10: **B90-B94 - Sequelae of infectious and parasitic diseases**
- ICD10: **K70-K77 - Diseases of liver**

Interventions/Observational Groups

- Arm 1: **Pediatric patients aged between 1 and 18 years.**
  For quantification of liver enzymes (ASAT, ALAT, Gamma-GT, alkaline phosphatase, bilirubin (total, direct and indirect) and albumin) blood samples are taken two times, first at study entry and second 3-7 days later or at clinical discharge.

Every patient receives a nasal lavage with physiologic salt solution (NaCl) within 24 hours after study entry for detection of viral pathogens by means of PCR (Polymerase-Chain-Reaction).

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Detection of the frequency of liver involvement during acute respiratory tract infections in pediatric patients.
Blood sampling at study entry and 3-7 days later for quantification of serum levels of liver enzymes.

Secondary Outcome

Which viruses are mainly responsible for the respiratory infections?
Which viruses may cause hepatic infection?
Identification of viral pathogens by means of PCR (Polymerase-Chain-Reaction).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik für Kinder- und Jugendmedizin am EVK, Hamm**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/06**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2014/01/06**

- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **1 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

1. Patients between 1 and 18 years old.
2. Diagnosis of uncomplicated upper or lower respiratory tract infection (rhinitis, sinusitis, pharyngitis, bronchitis, interstitial or central pneumonia). Diagnosis of pneumonia not exceeding 30% of included patients.
3. Written informed consent of patients and their parents.
4. For hospitalized patients blood sampling and nasal lavage should take place within 24 hours after hospital admission.

Exclusion criteria

1. Severe infections requiring assisted respiration or circulatory support via drug therapy.
2. Known or suspected congenital malformation or metabolic dysfunction which may influence study results.
3. Bronchopneumonia, pleuropneumonia and segmental pneumonia.
4. Infections already existing for more than five days.
5. Pre-existing icterus.

Addresses

- **Primary Sponsor**

Klink für Kinder und JugendmedizinEVK Hamm
Mr. Prof. Dr. Wolfgang Kamin
Werler Str. 130
59063 Hamm
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***

Primary Sponsor

Klink für Kinder und JugendmedizinEVK Hamm
Mr. Prof. Dr. Wolfgang Kamin
Werler Str. 130
59063 Hamm
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Klinik für Kinder und Jugendmedizin am EVK Hamm
Mr. Prof. Dr. Wolfgang Kamin
Werler Str. 130
59063 Hamm
Germany

Telephone: **02381-5893475**
Fax: **[---]***
E-mail: **WKamin at evkhamm.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik für Kinder und Jugendmedizin am EVK Hamm
Mr. Prof. Dr. Wolfgang Kamin
Werler Str. 130
59063 Hamm
Germany

Telephone: **02381-5893475**
Fax: **[---]***
E-mail: **WKamin at evkhamm.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
76227 Karlsruhe
Germany

Telephone: **[---]***

Commercial (pharmaceutical industry, medical engineering industry, etc.)

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Str. 4
76227 Karlsruhe
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.