

Trial Description

Title

Inflammatory cytokines in sera and bronchoalveolar lavage as prognostic marker in children with severe respiratory failure

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This study aims to gain new important insights about the prognostic value of levels of different inflammatory cytokines in sera and bronchoalveolar lavage (BAL) of children with acute respiratory distress syndrome (ARDS). ARDS is a rare, but very severe disease in childhood.

Eligible children which are treated on ICU for ARDS will be recruited and measurement of different inflammatory markers in sera and BAL will be performed. As control patients we will include rather healthy patients who need these diagnostic means, too. These patients are for example patients with recurring unexplained cough. This is only done when taking a blood sample and bronchoscopy is medically indicated in these children. Thus, there are no additional risks for children participating in this study.

The aim of the study is to enable a better prediction of the severity and course of ARDS by knowing the involved inflammatory markers. This could enable a better therapy and the development of new therapeutic agents.

Brief Summary in Scientific Language

Acute respiratory distress syndrome (ARDS) is an inflammatory disease of the lower airways, which is characterised by an increased permeability of the small vessels leading to hypoxemia and a high mortality. Each year about 10 out of 100.000 children are affected, the incidence is increasing.

Several studies in adults with ARDS have demonstrated that the levels of different cytokines in sera and bronchoalveolar lavage (BAL) are good markers for the development and further course of ARDS. Cytokines are expressed by different cells of the lung itself like bronchial epithelial cells, fibroblasts and alveolar macrophages as well as migrating blood cells like neutrophils, lymphocytes, monocytes and platelets as local or systemic inflammatory response. This inflammation can provoke persisting damage of the lungs. So far, no such studies have been performed in children,

Thus the aim of this study is to recruit children suffering from ARDS. Following written informed consent - sera and BAL are sampled. As control group we will include patients who undergo bronchoscopy with bronchoalveolar lavage and blood examination but are not mechanically ventilated. These patients need diagnostic procedures to exclude for example laryngomalacy or to get more information on unexplained tracheal cough. Participation in this study is only

possible, when taking a blood sample and bronchoscopy are performed due to medical reasons in these children.

The concentration of different inflammatory cytokines will than be measured by ELISA in sera and BAL and statistically analysed. This should enable the identification of positive and negative predictive values of different cytokines' levels for the development and severity as well as the survival of pediatric ARDS.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000510**
- Date of Registration in DRKS: **2010/09/16**
- 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.: **120/10 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **J96 - Respiratory failure, not elsewhere classified**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**



Study Type: **Non-interventional**

- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Correlation of inflammatory cytokines in BAL and sera with severity of pediatric acute respiratory syndrome (days of ventilation, oxygenation index).

Secondary Outcome

Correlation of inflammatory cytokines in BAL and sera with severity of pediatric acute respiratory -depending of the cause of ARDS

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2010/09/21**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **1 Months**
- Maximum Age: **17 Years**

Additional Inclusion Criteria

Mechanically ventilated children aged >1 month to < 18 years who need bronchoalveolar lavage and blood examination due to medical and therapeutic reasons. For example, BAL might be needed for microbiological testing and a directed antibiogram. As control group we will include patients who undergo bronchoscopy with bronchoalveolar lavage and blood examination but are not mechanically ventilated. These patients need diagnostic procedures to exclude laryngomalacia and get more information on unexplained tracheal cough.

Exclusion criteria

Severe concomitant diseases, like congenital lung malformation, immune deficiency or increased cerebral pressure and instability of cardiovascular circulation after manipulation.

Addresses

■ **Primary Sponsor**

ZKJ

Mr. PD Dr. Marcus Krüger

Mathildenstr. 1

79106 Freiburg

Germany

Telephone: **0761-2704301**

Fax: **0761-2704312**

E-mail: **marcus.krueger at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Scientific Queries**

ZKJ

Mr. Dr. Holger Meinicke

Mathildenstr. 1

79106 Freiburg

Germany

Telephone: **0761-2704301**

Fax: **0761-2704450**

E-mail: **holger.meinicke at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Public Queries**

Contact for Public Queries

ZKJ

Mr. Dr. Holger Meinicke

Mathildesstr. 1

79106 Freiburg

Germany

Telephone: **0761-2704301**

Fax: **0761-2704450**

E-mail: **holger.meinicke at uniklinik-freiburg.de**

URL: [---]*

Sources of Monetary or Material Support

- **Institutional budget , no external funding (budget of sponsor/PI)**

ZKJ

Mr. PD Dr. Marcus Krüger

Mathildenstr. 1

79106 Freiburg

Germany

Telephone: **0761-2704301**

Fax: **0761-2704312**

E-mail: **marcus.krueger at uniklinik-freiburg.de**

URL: [---]*

Status

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

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.