PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

SFB/TR22 - Allergic immune reaction in the lung

Trial Acronym

SFB A22: CLARA study

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is to better understand the development of allergic diseases, primarily asthma, in childhood. This may offer new options for preventive and therapeutic strategies. We are interested in differences in regulation of the immune system when asthma development has its onset. In this study we include children at the age of 4-14 years. After detailed clinical examination and diagnostics they are defined in 3 groups (allergic asthmatics, non-allergic asthmatics and healthy controls).

Brief Summary in Scientific Language

Allergic asthma in childhood is described as a dysregulation of the immune system in favor of a pro-allergic Th2 phenotype. The Th2/Th1-imbalance may be mediated by dysregulation of regulatory T cells and potentially also by interaction with pro-inflammatory Th17 cells. Both the allergic and non-allergic asthma phenotype are clinically relevant. The focus of this project is the investigation of regulatory T- and Th17 cells in interaction with Th1/Th2-cells in children with allergic and non-allergic asthma.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004635**

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- Date of Registration in DRKS: **2014/04/23**
- 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.: **379-08 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **J45.9 - Asthma, unspecified**
- ICD10: **J45.0 - Predominantly allergic asthma**
- ICD10: **J45.8 - Mixed asthma**

Interventions/Observational Groups

- Arm 1: **Allergic asthmatics**

  (clinical examination, lung funciton, measurement of exhaled nitric oxide, blood withdrawal, throat swab)
- Arm 2: **Non-allergic asthmatics**
  (clinical examination, lung funciton, measurement of exhaled nitric oxide, blood withdrawal, throat swab)
- Arm 3: **Healthy controls**
  (clinical examination, blood withdrawal, throat swab)

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
-

Study Type: **Non-interventional**

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Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Other**

Purpose: **Other**

- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Characterization of T cell marker

Secondary Outcome

Characterization of immune regulation in peripheral blood mononuclear cells.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Dr. von Haunersches Kinderspital, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/02/02**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

-

Gender: **Both, male and female**

- Minimum Age: **4 Years**
- Maximum Age: **14 Years**

Additional Inclusion Criteria

Inclusion criteria:
Age 4-14, recurrent pulmonary infections with airway obstruction / wheeze, more than 3 doctor´s diagnosed obstructive bronchitis. Intake of short-or long- acting beta 2-agonists, inhaled corticosteroides, leukotriene antagonists. Detailed clinical examination including lung-function.

Exclusion criteria

Exclusion criteria for asthmatics:
Any other pulmonary diseases (e.g. cystic fibrosis, bronchopulmonary dysplasia), any other chronic diseas, autoimmune diseases, immune deficiency, fever 14 day before inclusion, intake of antibiotics and probiotics 14 day before inclusion, intake of corticosteroides 14 days before inclusion, hypersensitization-therapy

///

Exclusion criteria for healthy controls:
Any pulmonary diseases (e.g. cystic fibrosis, bronchopulmonary dysplasia), any allergic diseases, any other chronic diseas, autoimmune diseases, immune deficiency, fever 14 day before inclusion, intake of antibiotics or probiotics 14 day before inclusion

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Kennedyallee 40
53175 Bonn
Germany

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

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*