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

Trial Description

Title

Post-infectious reprogramming and its association with persistence and chronicity of respiratory allergic diseases

Trial Acronym

PreDicta-WP1

URL of the trial

http://www.molekulare-pneumologie.uk-erlangen.de/e1846/e228/index_ger.html

Brief Summary in Lay Language

Allergic asthma is a chronic inflammatory disease of the airways. There are two different types of this disease: the allergic and the non-allergic asthma. Additionally, it is known that virus infections – especially those caused by the humane rhinovirus – are the most frequent reasons for the acute aggravation of allergic asthma. Different factors can induce asthma in small children. These factors are genetic or environmentally determined . The latter component is often due to bacteria or viruses infections of the airways. The main purpose of this study is to investigate the influence of virus infections on the process of the asthmatic trait and to associate it with the underlying changes in immune response.
In the PreDicta study there will be a group of 40 patients (asthma) and a control group of 20 children (no asthma) examined over a period of 24 months. At the beginning and at the end of this period the blood and the Nasal Faryngel Fluid of these children will be analyzed with different tests.

Brief Summary in Scientific Language

To this aim, not-interventional observations will be performed in the group of patients with asthma (n = 40) and a control group (no asthma; n = 20) at 4 to 6 years of age over a period of 24 months monitored/accompanied. From these patients there will be taken biological materials (blood, nasal swabs). This study investigates the influence of viruses (rhinovirus) and bacteria, which colonize the airways of children, on the Immune-pathogenesis of allergic asthma, in the time period between kindergarten and the beginning of the school age. To identify disease-specific-markers important for the diagnosis of this disease, analysis of the gene expression from PBMC and other not-invasive procedures (for example exhaled breath condensate) at the two indicated time points will be analyzed which
a) allows an advanced characterization of the molecular phenotypes)
b) identifies the pathogenetical differences between the two entities (boy/girl, age specific habits)
c) brings findings about the stability of the characteristics in a time schedule

related manner.

Organizational Data

- DRKS-ID: **DRKS00004914**
- Date of Registration in DRKS: **2013/05/16**
- 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.: **4435 , Ethik-Kommission der Friedrich-Alexander-Universität Erlangen-Nürnberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **J45 - Asthma**

Interventions/Observational Groups

- Arm 1: **Arm 1 Children with Asthma:**
  - after 0 and 24 months: Recruitment Informed consent Baseline Questionnaire, PFR, NO, Spirometry, blood sample, NPSwap, Training for cards, Free-Running Test, Skin Prick Test
  - after 6, 12 and 18 month: Follow-up Questionaire Upload Data, PFR, NO, Free-Running Test, NPSwap, Training for cards
  - after 3, 9, 15 and 21 months: Telephone questionnaire
  - If during 24-months follow-up period a child develops a respiratory tract infection/cold or an exacerbation of asthma or a symptom score according to the diary cards bigger or equal 4 or a decrease in FEV1>15% or PEF>30% the parent will be instructed to call the study centre and arrange a visit to the clinic within the next two days in order to arrange a FeNO-Test and a NPSwap. Blood will be taken to get serum. 4 - 6 weeks after the same test will be taken.
- Arm 2: **Arm 1 Control Children:**
  - after 0 and 24 months: Recruitment Informed consent Baseline Questionnaire, PFR, NO, Spirometry, blood sample, NPSwap, Training for cards, Free-Running Test, Skin Prick Test

Characteristics

- Study Type: **Non-interventional**

Study Type: **Non-interventional**

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

Primary Outcome

After 0 and 24 month Genexpression with Real-Time PCR and ELISA from blood-PBMC (Peripheral Blood Mononuclear Cell)

Secondary Outcome

By each hospital visit Fractionated Exhaled NO (FeNO-Monitor)Measurement and daily FEV1 measurement by electronic spirometer, Microbiology Nasal Swabs (Collaboration Prof. Dr. Bogdan)

Countries of recruitment

- DE **Germany**
- GR **Greece**
- FI **Finland**
- PL **Poland**
- BE **Belgium**

Locations of Recruitment

- Medical Center **Universitätsklinikum Erlangen, Erlangen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/09/26**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/09/26**

- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **4 Years**
- Maximum Age: **6 Years**

Additional Inclusion Criteria

- Mild to moderate persistent severity according to updated International Guidelines
- Written informed consent from the child’s parents/guardian’s
- Gestational age 36 weeks or above
- A diagnosis of asthma within the last 2 years, confirmed by a doctor of the participating study centre
- 3 episodes in the preceding 12 month (1 in the last 6 months)
- The child is able to perform at least a Peak Expiratory Flow (PEF) maneuver
- The legal custodian has the verbal, writing and mental ability to understand the intent and character of the study
- Age 4-6 years (beginning at the day of the 4th birthday and ending at the day of the 6th birthday)

Exclusion criteria

- Severe/brittle asthma
- Children receiving immunotherapy
- More than 6 courses of oral steroids during the proceeding 12 months
- Other chronic respiratory diseases (CF, BPD, immunodeficiencies) except allergic rhinits
- other chronical diseases or permanent medical treatment except for allergic exzema

Addresses

- **Primary Sponsor**

  Universitätsklinikum Erlangen
  Anästhesie / Molekulare Pneumologie
  Ms. Prof. Dr. Dr. Susetta Finotto

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.)**

European Commission
DG Research - Uni F06
CDMA 02/069
Mr. Gergios Zisimatos

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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CDMA 02/069
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1049 Brüssel
Belgium

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

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

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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.*