

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

Trial Description

Title

Lung function and airway hyper reactivity in late preterm and term infants after severe RSV infection in comparison to healthy controls

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

lung function in infants can be influenced i.e. by viral respiratory infection or prematurity. We therefore examin lung function in infants with and without prematurity and with and without respiratory infections

Brief Summary in Scientific Language

Respiratory syncytial virus (RSV) is the most common agent causing upper and lower airway tract infection in infants. Nearly all children are infected at least once by RSV at the age of two years and about every 50th child has to be hospitalised during the course of disease. Besides acute symptoms like cough, wheezing and dyspnoe, RSV is supposed to cause long acting sequels like chronic cough and airway hyper reactivity. The results of this study might have important implications for therapy and prophylaxis of RSV infection. For example, it might help to identify children at highest risk to develop impaired lung function after RSV infection and thus enable a more specific prophylaxis of the disease by passive immunisation (palivizumab). Besides we will gain data about the lung growth in preterm and term children in early infancy. These data can be used in counselling parents about the expected lung development in their child

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004424**
- Date of Registration in DRKS: **2013/12/20**
- 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.: **324/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **J12.1 - Respiratory syncytial virus pneumonia**
- ICD10: **P07.2 - Extreme immaturity**

Interventions/Observational Groups

- Arm 1: **preterm and term infants without lower respiratory tract infection, baby lung function; FEF (0.75)**
- Arm 2: **term and preterm infants with lower respiratory tract infection, baby lung function testing, FEF (0.75)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Forced expiratory flow (0.75) at one year of age

Secondary Outcome

forced expiratory flow (0.75) in term an preterm infants

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Josefskrankenhaus Freiburg, 79104, Freiburg im Breisgau**
- Medical Center **ZKJ Uniklinikum Freiburg, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/10/15**
- Target Sample Size: **39**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Months**
- Maximum Age: **12 Months**

Additional Inclusion Criteria

for RSV group:

positive RSV-test (ELISA/ PCR in nasopharyngeal aspirate) plus any of the follwing

- wheezing

Exclusion criteria

- **congenital heart defect**
- **pre-existing lung disease**
- **immune deficiency**
- **obvious skeletal thoracic malformation**



Addresses

■ Primary Sponsor

**ZKJ, Universitätsklinikum Freiburg
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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

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

AbbVie, Mainzer Straße 81, 65189 Wiesbaden
Max-Planck-Ring 2a
65105 Wiesbaden
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.abbvie.com**

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

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Status

■ **Recruitment Status: Recruiting stopped after recruiting started**

■ Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": **Anderer**

■ Reason, if Reason for Recruiting Stop "Other": **Technical problems due the lung function machine.**
No valid data reproducible

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Date of Registration in DRKS: **2013/12/20**

Date of Registration in Partner Registry or other Primary Registry: [---]*

- Study Closing (LPLV): **2020/12/02**
- Number of Participants in Germany after Recruiting complete: **5**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **5**

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.