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

Trial Description

Title

Attention to Infants at Respiratory Risks

Trial Acronym

AIRR

URL of the trial

http://www.klinikum.uni-muenchen.de/Klinik-und-Poliklinik-fuer-Frauenheilkunde-und-Geburtshilfe-Grosshadern/de/perinatalzentrum/neonatal_research/airr_studie/index.html

Brief Summary in Lay Language

Chronic lung disease in the very preterm infant increases the risk for pulmonary and neurologic sequelae persisting into adulthood. While mechanical ventilation (MV) and oxygen therapy offer life saving treatment to this patient population, they mainly contribute to the development of this disease. A profound understanding of the molecular mechanisms still remains elusive and early markers that allow the prediction of BPD development and the progression of this disease in the preterm infant are urgently needed.

As the routine investigation of human pulmonary tissue in preterm infants during the phase of mechanical ventilation is impossible, we will implement a screening approach in order to identify key molecules serving as early surrogate markers for the development of lung injury. Here, a panel of parameters will be investigated in different body fluid specimen to monitor the course of lung disease and predict its severity in this patient cohort. The identified surrogate markers will be interpreted in the context of lung function testing and advanced imaging technologies that are implemented to better define the functional and structural changes in these patients.

This project will help to understand characteristic mechanisms and enable the early diagnosis of lung alterations that are suitable for treatment decisions aimed to prevent the development of chronic lung disease in the preterm infant.

Brief Summary in Scientific Language

Bronchopulmonary dysplasia (BPD) is a chronic pulmonary disorder affecting more than 30% of all very preterm infants that increases the risk for pulmonary and neurologic sequelae persisting into adulthood. While mechanical ventilation (MV) and oxygen therapy offer life saving treatment to this patient population, they mainly contribute to the development of this disease. A profound understanding of the molecular mechanisms regulating the characteristically impaired alveolar and vascular development still remains elusive and early markers that allow the prediction of BPD development and the progression of this disease in the preterm

infant are urgently needed.

The overall aim of the proposed project is to shed light into the molecular mechanisms underlying BPD and to identify biomarkers that allow for the early diagnosis of the disease. As the routine investigation of human pulmonary tissue in preterm infants during the phase of mechanical ventilation is impossible, we will implement a screening approach in order to identify key molecules serving as early surrogate markers for the development of lung injury in response to MV. Here, a panel of parameters will be investigated in different body fluid specimen to monitor the course of lung disease and predict the severity of BPD in this patient cohort. The identified surrogate markers will be interpreted in the context of lung function testing and advanced imaging technologies that are implemented to better define the functional and structural changes in BPD in these patients beyond current clinical definitions.

This project will help to I) understand characteristic pathophysiologic changes in BPD and II) enable the early diagnosis of lung alterations that are suitable for treatment decisions aimed to prevent the development of BPD.

Organizational Data

- DRKS-ID: **DRKS00004600**
- Date of Registration in DRKS: **2013/01/28**
- 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.: **195-07 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1138-1384**

Health condition or Problem studied

- ICD10: **P27.1 - Bronchopulmonary dysplasia originating in the perinatal period**

Interventions/Observational Groups

- Arm 1: **Preterms with a gestational age up to 32+0 weeks will be prospectively included in the study. Urine, tracheal aspirates and serum samples will be obtained in clinical routine. Lung function and MRI will be performed upon discharge at about 36 weeks.**
  Infants that develop BPD will be compared to infants that do not develop BPD.

Characteristics

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

Primary Outcome

Statistical significance for a biomarker and proval with a different method.

Secondary Outcome

Reaching the limitations of the approved n-number.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Perinatalzentrum Grosshadern, München**
- University Medical Center **Neonatologie des UKGM, Giessen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/26**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **24 Weeks of pregnancy**
- Maximum Age: **32 Weeks of pregnancy**

Additional Inclusion Criteria

Included will be all preterm infants up 32+0 weeks gestational age, that are born and treated in the Perinatal Center Grosshadern or the Department of Neonatology in Giessen (UKGM)where parental informed consent can be obtained. Gestational age will be determined by the gynecologist either by calculation or sonographic determination. If gestational age is unclear, sonographic findings from the early pregnancy will serve as reference value.

Exclusion criteria

- Severe congenital abnormalities with cardiopulmonary dysfunction that cannot be survived (Ebstein anomaly, hypoplastic left ventricle, pulmonary hypoplasia following ahydramnion, Total Anomalous Pulmonary Venous Connection)

- Congenital diaphragmatic hernia, trisomie 13 and 18 and metabolic defects that lead to severe compromise for the organism

- Palliativ treatment decided in the first 10 minutes of life

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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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.*