**Trial Description**

**Title**

Nasal noninvasive high frequency oscillatory ventilation in premature infants below 32 weeks gestational age - a pilot study

**Trial Acronym**

Nasal HFOV for premature infants

**URL of the trial**

[---]*

**Brief Summary in Lay Language**

Preterm infants need respiratory support after being born. If they suffer from only mild respiratory distress the baby breathing might be assisted by a small nasal mask providing a constant air flow, this mode being called CPAP. It has shown that this kind of so called non invasive respiratory support may help those preterm infants to stabilize their breathing and contributes to avoid more invasive means of respiratory support. We are researching whether CPAP might actually be more effective when an oscillating air flow is being used. Our aim is to determine if these oscillations might improve respiratory stability in term of levels of carbon dioxide in these infants.

**Brief Summary in Scientific Language**

Nasal high frequency oscillatory ventilation (nHFOV) is a new mode of noninvasive neonatal respiratory support. An oscillatory pressure waveform is applied over a constant gas flow to the airways using a nasal or nasopharyngeal interface thus combining effects of nasal continuous positive airway pressure (nCPAP) and high frequency oscillatory ventilation. nHFOV is described both in bench studies and case series to be superior to nCPAP in terms of CO2 elimination and is utilized in an number of neonatal unit throughout Europe. However, there are no randomised controlled trials comparing nHFOV to any other mode of respiratory support. In this trial we are treating premature infants < 32 weeks of gestational age with 4 hours of nCPAP and 4 hours of nHFOV in an crossover design. Infants will be randomly assigned to the sequence of mode of respiratory support. Infants received surfactant or were extubated less than 24 hours prior to randomization. We hypothesise nHFOV to be significantly more effective in terms of CO2 elimination compared to nCPAP.

**Organizational Data**

- **DRKS-ID:** DRKS00007171
- [---]*
**Secondary IDs**

- Sponsor-ID: [---]*
- Other Secondary-ID: [---]*

**Health condition or Problem studied**

- Free text: **CO2 clearance using nasal high frequency oscillation**
- ICD10: [---]* - [---]*

**Interventions/Observational Groups**

- Arm 1: Premature infants < 32 weeks of gestational age will be treated 4 hours with nCPAP and 4 h with nHFOV using a crossover design within 24 hours after being extubated or receiving surfactant. Allocation to the treatment sequence will be randomized. CO2-Partial pressures after 4 h of each treatment will be compared.
- Arm 2: **nCPAP (4h) - nHFOV (4h)**

**Characteristics**

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
Study Type: Interventional
Study Type Non-Interventional: [---]*
Allocation: Randomized controlled trial
Blinding: [---]*
Who is blinded: [---]*
Control: Active control (effective treatment of control group)
Purpose: Treatment
Assignment: Crossover
Phase: N/A
Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): No

Primary Outcome

Invasive measurement of partial pressure of carbon dioxide after 4 h nHFOV vs 4 h nCPAP

Secondary Outcome

- Amplitude to achieve visible, adequate oscillation
- mean airway pressure
- need for intubation (failure of noninvasive ventilation per period)
- Number of apnea/bradycardia per period
- Respiratory rate*
- Heart rate*
- EDIN-Painscore*
- SpO2*
- FiO2*
- pO2*
- Transcutaneous pCO2

*after 4 hours of each type of ventilation

Countries of recruitment

- DE Germany

Locations of Recruitment

- University Medical Center Abteilung für Neonatologie und neonatologische Intensivmedizin, Freiburg im Breisgau
Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2014/07/20
- Target Sample Size: 26
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: no minimum age
- Maximum Age: 28 Days

Additional Inclusion Criteria

1. Premature infants < 32 weeks gestational age
2. 0-24 h after extubation or 0-24 hours after application of Surfactant
3. Respiratory insufficiency on non-invasive respiratory support (nasal CPAP)
4. PCO2 > 45 mmHg
5. Informed consent of caretakers

Exclusion criteria

1. Upper airway malformation leading to incompatibility with noninvasive ventilation
2. Known chromosomal abnormalities
3. Palliative/comfort care only.

Addresses

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Sources of Monetary or Material Support

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

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Status

Recruitment Status: Recruiting complete, follow-up complete
Study Closing (LPLV): 2016/09/23
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.