

Trial Description

Title

Impact of noise to intermittent hypoxia and bradycardia in preterm infants. A randomized controlled trial.

Trial Acronym

NAOP

URL of the trial

[---]*

Brief Summary in Lay Language

To test the impact of noise protection on the occurrence of apnea and bradycardia in 31 preterm infants. Premature infants have a common problem that they make pauses in breathing and the heart beats are too slowly. We want to test if an ear protection against untypical neonatal noise brings better outcome for breathing and heart beat.

Brief Summary in Scientific Language

Apnea of prematurity can cause serious problems. Environmental acoustic stimuli may cause agitation and seem to play an important role. We aim to evaluate the occurrence of pulse oximetry-derived desaturation and bradycardia under continuous environmental noise recording in a randomized controlled trial including 31 preterm infants. By using a cross-over study design, subjects receive and do not receive noise protection for 2 hours each in a randomized order. A clinically relevant and statistically significant reduction in the occurrence of hypoxia and bradycardia should be proven.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003433**
- Date of Registration in DRKS: **2012/05/10**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **245/2012BO1** , **Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1129-7733**

Health condition or Problem studied

- ICD10: **R06.8 - Other and unspecified abnormalities of breathing**
- ICD10: **P07.2 - Extreme immaturity**

Interventions/Observational Groups

- Arm 1: **cross-over design: MiniMuffs® as an ear protection then no intervention**
- Arm 2: **cross-over design: no intervention then MiniMuffs® as an ear protection**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **assessor, data analyst**
- Control: **No treatment**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Occurrence of pulse oximeter saturation below 80% per h, measurements last 2 h with and 2 h without intervention (ear protection).

Secondary Outcome

Occurrence of heart beat under 80 beate per minute per h, measurements last 2 h with and 2 h without intervention (ear protection).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Kinder- und Jugendmedizin; Abt. IV Neonatology, Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/09**
- Target Sample Size: **31**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **24 Weeks**
- Maximum Age: **37 Weeks**

Additional Inclusion Criteria

Patients of the local neonatal intensive care unit; presentation of apnea of prematurity; parents agreement

Exclusion criteria

Redemption of the parents agreement

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

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

Universitätsklinikum für Kinder- und Jugendmedizin; Abt. IV Neonatologie
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■ **Private sponsorship (foundations, study societies, etc.)**

**Medizinische Fakultät Tübingen; Bereich Akademische Angelegenheiten; IZKF
Promotionskolleg**

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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/12/12**

Trial Publications, Results and other documents

- Paper **A Randomized Controlled Trial on the Effect of Earmuffs on Intermittent Hypoxia and Bradycardia in Preterm Infants**
- Abstract **Einfluss eines Gehörschutzes gegen Lärm neonataler Intensivstationen auf intermittierende Hypoxien und Bradykardien Frühgeborener. Eine randomisierte, kontrollierte Interventionsstudie**

* 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.