

Background

Newborns exposed to opioids *in utero* and infants born prematurely require lengthy hospitalization in the Neonatal Intensive Care Unit (NICU) where they are often exposed to loud noises that are potentially harmful to the developing infant:

- Disrupt sleep
- Impair autonomic function
- Prolong recovery
- Compromise outcomes

NEATCAP Device – DREAMIES™ (NEATCap Medical, LLC)



Researchers

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Purpose

Pilot study to evaluate
**“Neurosensory, Environmental,
 Adaptive Technology” –
 NEATCAP Device.**

Hypothesis: NEATCAP Device, a circumaural hearing protection device that dampens unsafe NICU noise, improves sleep and cardio-respiratory function in critically-ill infants treated in the NICU.

Primary Outcomes:

- Increase sleep duration
- Improve sleep quality
- Reduce cardio-respiratory events

Study Design

UMMS IRB Docket H00015487

Subjects

- 5 premature infants (<37 wks GA); studied at 32 and 36 wks PCA
- 5 opioid exposed full-term newborns

Methods

- Single-session bedside study UMMH NICU
- Within-subject design, convenience sample
- Full polysomnography recordings
- Compare physiology: NEATCAP Device ON vs OFF
- Wake vs Sleep States (Active, Quiet, Indeterminate)
- Cardio-respiratory (bradycardia, tachycardia; apnea, tachypnea)
- Thermoregulation
- Blood-oxygen saturation
- Movement –index of irritability
- Volume of feeds

Consultants

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Intellectual Property

2 patents filed by NEATCap, LLC

- 2015 US Pat. Appl. 14/625, 325
- 2018 US Pat. Appl. 15/881, 111

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