NICU RESEARCH STUDIES

KNIRS

Study contacts:

Name	Role	Phone	Email
Matthew Harer, MD	PI	608-417-6236	mwharer@wisc.edu
Shayla Schwingle	Lead Research Coordinator	608-263-7608	snschwingle@wisc.edu
Cassie Nelson	Research Nurse	608-890-1589	Cenelson4@wisc.edu
Bridget Johnson	Clinical Research Manager	608-264-1400	Bridget.johnson@pediatrics.wisc.edu

Purpose of the study:

- The purpose of the study is to evaluate how well a skin-monitoring device called NIRS (Near Infrared Spectroscopy) can detect signs of kidney injury and signs of brain injury in babies born prematurely. The NIRS skin-monitor measures the amount of oxygen going to a specific tissue where a sensor is placed.

Where is the study taking place?

- Meriter NICU
- AFCH NICU

Study Procedures:

- The study team will collect the data from the NIRS monitor and collect data for the duration of the study from their medical record.
- Twice within the first 14 days of life the study team will do bilateral monitoring and have a sensor placed on each kidney.
- Once within the first 14 days of life Dr. Harer will do a kidney ultrasound to determine where the kidney is in the body, how far it is from the skin, how big it is and if there are any abnormalities.
- After the babies are removed from SOC NIRS monitoring the study team will do weekly NIRS monitoring for 3 hours.

Inclusion:

- Admission to Meriter NICU at < 96 hours of age
- Birth prior to 32 weeks gestation
- English or Spanish speaking
- Consent obtained by 96 hours of age.

Exclusion:

- Congenital abnormality of the kidney or urinary tract (CAKUT) not including hydronephrosis
- Attending's physician discretion to not include in study due to clinical concerns.
- In the PI's medical opinion, there is a significant likelihood that the neonate would not survive the first 3 days of life.

NIRS Monitoring Frequently Asked Questions for Nurses:

Q: Why are we doing NIRS monitoring?
A: NIRS monitoring is standard of care for patients born under <32 weeks (more specific criteria below or in clinical guideline). Research procedures are done in addition to this standard of care monitoring. Research coordinators will instruct you on the research specific procedures.

Q: Who is placed on NIRS monitoring?
A: Neonates <32 weeks OR neonates with neonatal encephalopathy undergoing cooling OR neonates being evaluated for congenital heart disease

Q: How is this different from the NIRS research study?
A: The research study will continue.
We no longer need to use the "blinding" screens.
Parents will consent to using the NIRS data instead of applying the sensors.
We will continue to do 'extra things' for the study protocol – we will notify you!
- Bilateral Monitoring of right and left kidney for 3 hours twice in the first 10 days
- Kidney US by Dr. Harer between day 7-10
- Weekly monitoring for 3 hours until discharge. No alarms required. Chart hourly values.
- You may be asked to continue monitoring for specific medical events (ex. signs of AKI, PDA or IVH)

Q: What do the providers need to do?
A: Enter specific Epic order for qualifying babies called 'regional oximetry' with algorithm for values outside of normal range, when to notify a provider, and which site(s) to monitor.

Q: What do nurses need to do?
A: Apply sensors to babies with an order in Epic.
Troubleshoot and notify clinical providers when a value is alarming. These value ranges will be on a laminated cared on the machine.
Document NIRS numbers hourly (for SOC and weekly monitoring), also document location, site changes or other notes (ex. Applied or removed) when applicable in NIRS flowsheet (found in vitals flowsheet).

Q: How long do the sensors last before I should replace them?
A: Document time and date on each sensor with marker when placing on skin.
Discard and place fresh sensors every 5 days or sooner if needed (ex. Soiled sensors or not working)

Q: How often do I need to move the sensors?
A: <34 weeks - rotate sensors q6 hours
34 weeks or greater - rotate q 24 hours or more PRN

Q: When does continuous NIRS monitoring start or stop?
A: Neonates <32 Weeks
- Start monitoring at 24 hours after birth or sooner if skin allows
- Stop monitoring if ALL of the following conditions are met:
  - Off IV nutrition and medications
  - On 24 kcal fortified feedings

No hemodynamically significant PDA clinically noted (ex. PDA requiring medical treatment or considering surgical closure)

Neonates with neonatal encephalopathy undergoing cooling

Start monitoring on admission to NICU

Stop monitoring prior to brain MRI on Day 4 or 5

Neonates evaluated for congenital heart disease

Start monitoring on admission to NICU

Stop monitoring after discussion with Peds cardiology

Q: Do I need to use mepitel on the sensor to protect the infant's skin?

A: <34 weeks – use Mepitel on sensor to protect skin

34 weeks or greater – no mepitel required, may need to use as needed for sensitive skin

Q: What are the general alarm ranges for the NIRS values?

>37 weeks gestational age		
Organ	Upper Limit	Lower Limit
Cerebral (forehead)	85	55
Renal (flank)	90	60
Mesenteric (abdomen)	70	30
<37 weeks gestational age (pre term)		
Organ	Upper Limit	Lower Limit
Cerebral (forehead)	85	50
Renal (flank)	90	50
Mesenteric (abdomen)	70	30

The Epic order will include where to set the lower and upper limit of the alarms based on normative values for the gestational and chronological age of the baby

Nurses should notify a provider if values are outside of the ordered saturation range for more than 30 minutes despite measures noted in the 'Troubleshooting' section below.

If a baby is persistently outside of the desired range despite interventions, a provider can order for the alarm to be reduced or raised to a new level versus being silenced to avoid alarm fatigue. Determining whether to keep the alarm outside of the normal limits or silenced should be re-addressed daily.

Q: Can sensors be removed during K-cares or general cares?

A: Yes, sensors can be removed if they make these processes challenging or interfere with bonding.

Q: Why do the sensors still provide values when they aren't connected to my patient?

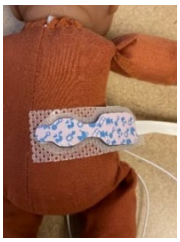
A: NIRS sensors read the room air. Please unplug the sensors from the port whenever they are not connected to the infant. This may skew NIRS values if the sensors read room air.

Q: I found the sensors placed on the wrong part of the infant. Do I need to tell the study team or document this?

A: Yes, please move the sensors to the correct location and document in Epic in the NIRS flow sheet by adding a comment.

Q: When I am putting the sensor on the baby, does it matter if the rounded end points medial or lateral?

A: The rounded point end should always toward the midline (towards the middle of the forehead or toward the spine). In other words, the blinking light should go over the organ we wish to capture.



Q: How do I work the NIRS machine?

A: When turning on the machine, make sure there is always a flash drive inserted at the back of the monitor and the date/time on the machine are correct

Enter patient MRN as the patient ID

Plug into red outlets in the event of an electrical outage.

Q: What if my sensors aren't providing a reading?

A: Make sure probe has complete contact with the skin while ensuring there is no pressure above the sensor.

Check the cable and sensor connections.

If the connections are tight and still not providing a reading, try a new sensor/cable.

If rSO2 readings are not consistent or are not displaying:

Check for light interference and consider covering the sensor

If the sensor is placed over adipose tissue or edema greater than three (3) cm the light will not reach the tissue bed. Remove or move the sensor to another location.

If readings are constant without variability, this requires an evaluation of the location.

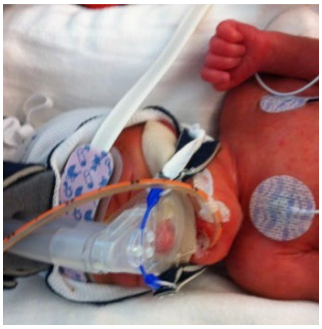
Q: How do I place the NIRS sensors?

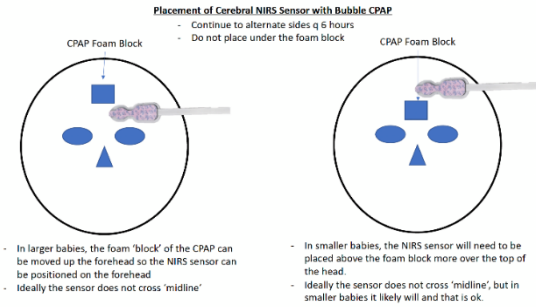
A: Cerebral (forehead)

Above the eyebrow and below the hairline. Ideally either right or left of midline.

For babies on CPAP – the sensor cannot go directly below the foam – the pressure from the foam could cause skin injury! Consider the following placement:

- Below the foam and above the eyebrow
- Above the foam on top of the hair





A: Renal (flank)

Above the iliac crest and below the last rib in the soft tissue space.

Horizontally placed with light emitting tip closest to the spine but not over the bone. If the light emitting tip is placed on the anterior abdomen or side, it will read intestinal oxygenation.

Happy Baby Hearts

Study contacts:

Name	Role	Phone	Email
Matthew Harer, MD	PI	608-417-6236	mwharer@wisc.edu
Shayla Schwingle	Lead Research Coordinator	608-263-7608	snschwingle@wisc.edu
Cassie Nelson	Research Nurse	608-890-1589	Cenelson4@wisc.edu
Bridget Johnson	Clinical Research Manager	608-264-1400	Bridget.johnson@pediatrics.wisc.edu

Purpose of the study:

- The purpose of the study is to see if NIRS monitoring can be used in the Newborn Nursery, NICU and PICU to help detect CoA. The study will also evaluate nursing and parental satisfaction with NIRS monitoring compared with periodic blood pressure and pulse ox checks that are currently done to monitor newborns at risk of developing CoA.

Where is the study taking place?

- Meriter Newborn Nursery
- Meriter NICU
- AFCH NICU
- AFCH PICU

Study Procedures:

- Babies will be monitored with NIRS monitoring during their stay in the hospital. Their participation in the study will last as long as the NIRS monitors are attached. Typically, this is 2-4 days, but may be up to 2 weeks if admitted to a NICU or PICU.

Inclusion:

Neonates Inclusion Criteria:

- Delivered at ≥ 35 weeks of gestation.
- <12 hours of age
- Inpatient at Meriter Hospital, Inc. NICU or Newborn Nursery or AFCH PICU or NICU
- Diagnosed as at risk for CoA.

Exclusion:

Neonate Exclusion Criteria:

- Major congenital anomalies of the kidney
- Attending's physician discretion to not place sensors due to clinical concerns
- In the PI's medical opinion, there is a significant likelihood that the neonate would not survive the first 3 days of life.

Help us improve care for newborns at risk for heart problems.

We invite primary caregivers and pregnant people with babies diagnosed as at risk for coarctation of the aorta (CoA) to participate in a research study.

Happy Baby Hearts Study

The Harer Research Group is conducting a study to determine if a monitoring device called NIRS (Near Infrared Spectroscopy) can be used to detect CoA. The study will also evaluate parents' and nurses' opinions about NIRS monitoring compared with periodic blood pressure and pulse oximetry checks, which are currently used to monitor for CoA in the newborn nursery.

If you decide to participate, your baby will have a sensor placed on their skin within 12 hours of birth. Typically, sensors are used to monitor babies for 2 to 4 days, but monitoring may continue up to 2 weeks if a baby is transferred to the NICU and needs cardiac surgery. You may also be asked to complete a brief survey about your opinion of the NIRS monitoring. Information will be collected from your and your baby's medical records.

Caregivers will receive $40 for joining the study. There are no direct benefits for participating in the study, but your participation may help us improve future outcomes for newborns diagnosed as at risk for CoA.

Interested? Have Questions?

608-228-4940

researchnurses@pediatrics.wisc.edu

Newborn Eligibility Criteria:

- Delivered at ≥ 35 weeks gestation
- Less than 12 hours old
- Diagnosed as at risk for CoA
- Current inpatient at Meriter Hospital NICU or Newborn Nursery **OR** the AFCH NICU or PICU

Caregiver Eligibility Criteria:

- Primary caregiver of the newborn participant
- Able to complete surveys in English or Spanish

This study is led by Dr. Matthew Harer, Department of Pediatrics, Neonatology.
202 South Park St.
Madison, WI 53715

UWHealthKids | School and Public Health, UNIVERSITY OF WISCONSIN-MADISON

IRB NUMBER: 2023-001
IRB APPROVAL DATE: 03/06/2023

UnityPoint Health
Meriter Foundation

Version 1.1, Jan 11, 2023

Healthy Little Eyes

Study contacts:

Name	Role	Phone	Email
Ryan McAdams, MD	PI	608-417-6377	mcadams@pediatrics.wisc.edu
Shayla Schwingle	Meriter Coordinator	608-263-7608	snschwingle@wisc.edu
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Bridget Johnson	Clinical Research Manager	608-264-1400	Bridget.johnson@pediatrics.wisc.edu

Purpose of the study:

- The purpose of this research study is to gather more information on how eye injury is related to a baby's future development and see if eye function and brain test results can be used, along with current measures, to better diagnose and treat babies with HIE.

Where is the study taking place?

- Meriter NICU
- AFCH NICU
- AFCH PICU
- NBFU Clinic

Study Procedures:

- NICU babies:
    - Babies will have eye exams twice while in the NICU. The first eye exam will occur during the first 6-78 hours of life. The second eye exam session would occur on approximately day 5 or 6 of life, ideally within 24 hours of the infant's brain MRI.
        - Visual Evoked Potential (VEP): This exam measures the time it takes for a visual stimulus to travel from the eye to the brain, and it helps diagnose retinal disease. Small gold-cup electrodes will be applied to your child's head using a small dot of adhesive paste. The handheld device is then connected to the electrodes, and the child's eyes are exposed to a light flicker. Each eye will be tested separately, and while testing one eye, the other eye may be patched.
        - Electroretinogram (ERG): This exam measures how well the light-sensitive retinal tissue is functioning. Skin electrodes will be place under each eye. Eyes are then exposed to a flashing light. Each eye will be tested separately, and while testing one eye, the other eye may be patched.
- NBFU Clinic babies:

- The infants who were diagnosed with HIE and present to the newborn clinics will undergo only one eye exam session. The eye exam session will include ERG and VEP.

Inclusion:

HIE Neonates Inclusion Criteria:

- Inpatient neonates diagnosed with HIE
- Pediatric patients who are less than 78 hours of age at the time of enrollment
- Subjects whose parent/legal guardian is able to complete consenting process in English

Exclusion:

HIE Neonates Exclusion Criteria:

- Subjects with prenatally diagnosed or congenital brain and/or eye abnormalities not associated with HIE, including but not limited to microphthalmia, anophthalmia, congenital cataract, eye or eyelid coloboma, congenital glaucoma, CMV retinitis, optic nerve hypoplasia, aniridia, cryptophthalmos, globe abnormalities.
- Subjects who have a known central nervous system illness other than HIE, including but not limited to congenital brain malformations or congenital hydrocephalus.
- Subjects whose parent/legal guardian is unable to provide informed consent, including subjects who are in foster care, subjects within state custody, and subjects of minor parents.
- The attending medical team does not approve.

HEALTHY LITTLE EYES STUDY

Visual function as a novel outcome measure following neonatal hypoxic-ischemic encephalopathy

Overview

The Healthy Little Eyes Study is enrolling neonates aged 0-78 hours with a diagnosis of hypoxic-ischemic encephalopathy (HIE); if you are caring for a patient who may be eligible, please contact the study team. Thank you in advance for your help!

The study involves two eye exam sessions. Each eye exam session consists of two visual function tests: a Visual Evoked Potential (VEP) and an Electroretinogram (ERG). Neonates will have their eyes examined twice - at around 1-3 days of life and again at about 1 week of life.

Contact Info

If you encounter a patient who may be eligible for the study, please contact:

- **Study Coordinator:** 608-228-4940
- **NICU Lead Researcher**: Ryan McAdams, MD

Inclusion Criteria

- Age 0-78 hours
- A diagnosis of HIE
- Parent/guardian able to consent in English

Purpose

The purpose of this research study is to gather more information on how eye injury is associated to a baby's future development. We want to see if visual functioning and brain test results can be used alongside current measures to better diagnose and treat babies with HIE.

We hope that information from this research may lead to improved care in the future for babies with HIE by diagnosing them early in life, leading to better developmental outcomes.

Version 1.1, dated 12/06/2022

Baby Brain Recovery

Study contacts:

Name	Role	Phone	Email
Dr. Bernadette Gillick	PI	608-262-3079	bgillick@wisc.edu
Veronika Mak	Lab Program Coordinator	608-381-2699	brainrecovery@pediatrics.wisc.edu
Ryan McAdams, MD	Med. Monitor	206-499-7886	mcadams@pediatrics.wisc.edu

Purpose of the study:

- We want to find out how the brain changes in babies after an early injury to the brain. We are doing this research because an early brain injury has the potential to influence development and movement. To provide early therapies at a time when the brain is still developing and recovering from the brain injury, we first need to understand how the brain may have changed after this early brain injury.

What will happen in this study?

- Two different options for enrollment
    - The Two-Year Option allows you to participate in the entire study. You will participate in study visits at four or five different time points. This study happens over the first two years of your child's life.
    - The One-Visit Option allows you to attend one study timepoint, when your child is between the age of 3-6 months. Families who select the One-Visit Option can choose to enroll in the Two-Year Option at any time.

Inclusion Criteria:

- Corrected gestational age between term and 6 months of age (e.g. -a baby born 8 weeks prematurely at 6 months will have the motor exam of a term 4-month old) at the Infant Visit
- Confirmed radiologically-confirmed acute unilateral or bilateral brain lesions, including perinatal stroke, neonatal hemorrhagic or thrombotic stroke, involving the motor cortex and/or subcortical structures, and intracranial hemorrhage, involving the motor cortex and/or subcortical white matter, periventricular leukomalacia, or hypoxic ischemic encephalopathy.
- Both parents/legal guardian (if applicable) are/is wiling and able to provide informed consent.
- At least one parent/legal guardian is able to complete study procedures in English
- At least one parent/legal guardian is willing and able to attend study visits at the University of Wisconsin-Madison

Exclusion Criteria:

- Metabolic disorder
- Had or has a neoplasm
- Disorder of cellular migration and proliferation
- Acquired traumatic brain injury
- Surgery that may constrain current spontaneous movements
- Indwelling metal, incompatible medial devices or other contraindications for MRI/TMS assessment
- Separate neurologic disorder unrelated to stroke/brain bleed/periventricular leukomalacia
- Experiences apneic episodes
- Syncope related to known heart defect
- Required any use of supplemental ventilation

- Experiences uncontrolled seizures (Note: Seizures are considered controlled if participants are taking a centrally acting medication and have no known seizures for the past 7 days.)

PEAPOD

Study contacts:

Name	Role	Phone	Email
Whitley Hulse, MD	PI	785-550-5827	Whulse@wisc.edu
Pam Kling, MD	Co-I	608-417-6236	pkling@wisc.edu
Sally Norlin, MS, RD	Clinical Adjunct Preceptor; Department of Pediatrics UPH Meriter NICU Lead Registered Dietitian	608-417-6023	Sally.norlin@unitypoint.org
Paige Conduit	Neonatal/Perinatal Fellow	616-481-9914	pcondit@wisc.edu
Shayla Schwingle	Clinical Research Coordinator	608-263-7608	snschwingle@wisc.edu

Purpose of the study:

- The overall purpose of the study is to understand how the nutrition the baby receives in the NICU affects their growth and future development, particularly neurodevelopment. We hope this study will help improve our understanding of the nutritional care we provide to each baby to positively impact their growth and future developmental outcomes.

What will happen in this study?

- As part of a neonates standard of care, once the neonate can tolerate 5 minutes of room air (able to maintain SpO2 without respiratory support or development of respiratory distress), body composition measurements using the PEAPOD Infant Body Composition measuring device will be obtained weekly through discharge from the NICU.
- After discharge, a repeat measurement will be obtained at Meriter Hospital during a follow-up visit when the baby is 3-4 months CGA.

Inclusion Criteria:

Neonate Inclusion Criteria:

- Born at Mertier Hospital, Inc ≤ 32 weeks GA.
    - All infants who are born ≤ 32 weeks GA are eligible for inclusion and will not be excluded based on birth weight percentile or diagnosis of: IUGR, SGA, AGA or LGA.

Exclusion Criteria:

Neonate Exclusion Criteria:

- Known genetic condition that impact neurodevelopmental outcomes or brain structure development.
- Multiple major congenital anomalies
- Will require transfer to American Family Children's Hospital (AFCH) prior to 36 weeks PMA.
    - Any neonate who enrolls in the study and then unexpectedly requires transfer to AFCH prior to 36 weeks CGA will be excluded from the study if they are unable to obtain at least one ADP body composition measurement prior to transfer. Body composition data points can only be collected at Meriter Hospital due to location of PEAPOD.

Lung POCUS to Predict Extubation Success

Study contacts:

Name	Role	Phone	Email
Adam Bauer, MD	PI	414-828-7316	adam.bauer@wisc.edu
Ann Chacko, DO	PI	414-828-7316	archacko@uwhealth.org

Purpose of the study:

- The objective of this study is to determine if lunch POCUS can predict extubation success.
- The primary purpose is to evaluate the utility of lung ultrasound score in predicting extubation success.
- The secondary objectives are to determine if there is a correlation between the postextubation lunch ultrasound score, the change in pre- and post-extubation lunch ultrasound scores, and the need for re-intubation.

What will happen in this study?

- Infants meeting inclusion criteria will be cared for by the bedside medical team as appropriate. The study team will be notified by the bedside team about anticipated date of extubation.
- A lunch ultrasound will be performed within 12 hours prior to extubation and a post-extubation lung ultrasound will be done within 36 for comparison.
- The study team will use monitors that will already be in place to collect vital signs of the neonates 5 minutes prior to performing POCUS and 5 minutes following POCUS.

Inclusion Criteria:

Neonate Inclusion Criteria:

- All infants born at Unity Point Health Meriter Hospital and University of Minnesota admitted to the NICU with respiratory distress requiring intubation.
- Meeting the following extubation readiness criteria as per the attending neonatologist.

Exclusion Criteria:

Neonate Exclusion Criteria:

- Known major congenital disease (chromosomal abnormality, heart disease, respiratory malformation)
- Neonates with parents that are less than 18 years old.

AERO-05

Study contacts:

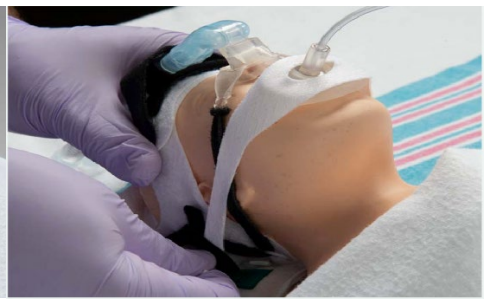
Name	Role	Phone	Email
Dinushan Kaluarachchi, MD	PI	347-279-5014	kaluarachchi@pediatrics.wisc.edu
Shayla Schwingle	Research Coordinator	608-263-7608	snschwingle@wisc.edu
Cassie Nelson	Research Nurse	608-890-1589	Cenelson4@wisc.edu
Bridget Johnson	Clinical Research Manager	608-264-1400	Bridget.johnson@pediatrics.wisc.edu

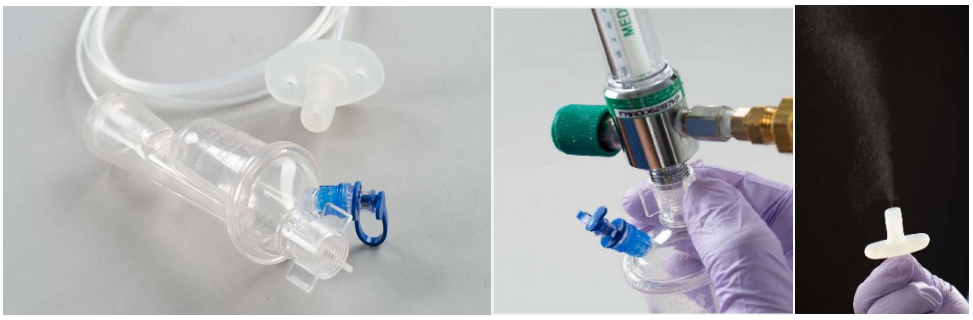
Purpose of the study:

- The purpose of this clinical study is to assess the effectiveness and safety of Infasurf delivered through the InfasurfAero, a novel nebulizer device specifically designed for administration of Infasurf without interrupting positive pressure nasal respiratory support.

What will happen in this study?

- This is a double-blinded study.
- There will be two groups.
    - Control group: The baby will receive low flow respiratory air alone through the InfasurfAero™ and will continue on nasal respiratory support as appropriate.
    - Intervention group: The baby will receive a single dose of Infasurf through the InfasurfAero™, a pacifier like device which is placed in the mouth and above the vocal cords, not through them, and the Infasurf is inhaled over 1 to 2 hours as an aerosolized mist. After surfactant is given, the InfasurfAero™ will be removed from the baby's mouth and may continue on nasal respiratory support as appropriate.





Inclusion Criteria:

Neonate Inclusion Criteria:

- Written informed consent obtained by parent or legal representative prior to or after birth
- Gestational age at birth ≥ 29 0/7 AND ≤ 36 6/7 weeks
- Birthweight ≥ 1,000 AND ≤ 3,500 grams
- Age ≥ 1 hour AND ≤ 6 hours
- Clinical diagnosis of surfactant-deficient RDS, with EITHER
    - A Silverman-Anderson Retraction Score ≥5 prior to placing on CPAP OR
    - Signs of respiratory distress (tachypnea, retractions, grunting) AND radiographic confirmation
- Requiring CPAP (i.e., Nasal continuous positive airway pressure)
- Respiratory Severity Score (RSS) ≥ 1.25 AND ≤2.4[c]
- If subject is >34 weeks' gestation a chest radiograph is required

[c] Adjusted to reflect partial pressure of supplemental oxygen at sea level for high altitude sites.

Exclusion Criteria:

Neonate Exclusion Criteria:

- Surfactant administration prior to randomization
- Mechanical ventilation prior to randomization
- Major congenital anomaly (suspected or confirmed)
- Abnormality of the airway (suspected or confirmed)

- Respiratory distress presumed secondary to an etiology other than RDS (e.g., suspected pulmonary hypoplasia, pneumothorax, meconium aspiration syndrome, pneumonia, septic or hypovolemia shock, hypoxic ischemic encephalopathy)
- Culture-positive bacterial sepsis requiring at least 5 days of antibiotic therapy.
- Apgar score <3 at 5 minutes of age
- Umbilical cord gas pH <7.0 or BD> 10
- Any condition that, in the opinion of the Investigator, would place the neonate at undue risk