A Partially-Blind, Randomized, Parallel-Group Dose Ranging Study to Determine the Efficacy, Safety and Tolerability of AeroFactTM (Aerosolized SF-RI 1) Administered by nCPAP versus nCPAP alone in the Treatment of Preterm Infants at Risk for Worsening Respiratory Distress Syndrome

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 26 Weeks to 31 Weeks old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Parental consent obtained prior to study procedures being performed (pre-natal consent is allowed) 2. 26 0/7 to 30 6/7 weeks of gestational age 3. Weight <2.0 Kg 4. Respiratory Severity Score (RSS) 1.4-2.0

Exclusion Criteria:

1. Apgar score less than or equal to 5 at five minutes after birth 2. Need for chest compressions or administration of epinephrine or bicarbonate in the delivery room 3. Premature rupture of membranes (PROM) > 14 days 4. Need for intubation and/or mechanical ventilation prior to enrollment 5. Active pneumothorax requiring chest tube 6. Significant congenital anomaly, chromosomal abnormality 7. Concomitant treatments with inhaled nitric oxide

Conditions & Interventions

Interventions:
Drug: AeroFact, Other: nCPAP
Conditions:
Respiratory Distress Syndrome in Premature Infant
Keywords:
Respiratory Distress Syndrome, BPD, surfactant, Preterm Infant

More Information

Description: A Partially-Blind, Randomized, Controlled, Parallel-Group Dose Ranging Study to Determine the Efficacy, Safety and Tolerability of AeroFactTM (SF-RI 1 surfactant for inhalation combined with a dedicated drug delivery system) in Preterm Infants at Risk of Worsening Respiratory Distress Syndrome. To determine an optimal dose of AeroFactâ„¢ administered to preterm infants on nCPAP or nIMV vs. nCPAP or nIMV alone in reducing the incidence of intubation/cannulation and bolus surfactant instillation in the first 7 days after birth. To evaluate pulmonary outcomes and respiratory resource utilization at 3, 6, 9, and 12 months PMA
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