

InfasurfAero™ Versus Sham Treatment in Preterm Newborns With RDS

NCT05960929

Status	RECRUITING
Phase	Phase 3
Sponsor	ONY
Enrollment	220 participants

Key Eligibility Criteria

Inclusion (8)

- Written informed consent obtained by parent or legal representative prior to or after birth
- Gestational age at birth e 29 0/7 AND d 35 6/7 weeks
- Birthweight e 1,000 AND d 3,500 grams
- Age e 1 hour AND d 6 hours
- Clinical diagnosis of surfactant-deficient RDS, with EITHER i. a Silverman-Anderson Retraction Score e 5 (in Room Air), OR ii. signs of respiratory distress (tachypnea, retractions, grunting) AND radiographic confirmation
- ... and 3 more (see full listing online)

Exclusion (8)

- 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)
- ... and 3 more (see full listing online)

Locations (10 total)

St. Josephs Hospital and Medical Center, Phoenix, Arizona, United States
Phoenix Children's, Phoenix, Arizona, United States
Sharp Mary Birch Hospital for Women & Newborns, San Diego, California, United States
... and 7 more locations

<https://clinicaltrials.gov/study/NCT05960929>

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