

Dead Space and Inhaled Nitric Oxide in Pediatric Acute Respiratory Distress Syndrome

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 0 years to 21 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Age >37 weeks corrected gestational age to 21 years, including adults lacking the capacity to consent.
- Within 72 hours of the start of invasive mechanical ventilation and meet the criteria for pediatric ARDS (new infiltrate on chest imaging and a known ARDS risk factor within 7 days of the onset of hypoxemia) and either meet criteria for moderate or severe pediatric ARDS between 4-72 hours of IMV ($OI \geq 8$ or $OSI \geq 7.5$) OR have an $OI \geq 20$ or an $OSI \geq 14$ x 15 minutes between 0-4 hours of IMV.
- Subgroup of children eligible for longitudinal Blood Collection: Children with severe PARDS ($OI \geq 16$ or an $OSI \geq 12$ between 4-72 hours of IMV) or those with an $OI \geq 20$ or an $OSI \geq 14$ for 15 minutes between 0-4 hours of IMV will be eligible for collection of longitudinal plasma samples.

Exclusion Criteria:

- Non-conventional invasive mechanical ventilation (i.e. High Frequency Oscillatory Ventilation, Airway Pressure Release Ventilation) at the time of ICU admission
- ECMO or iNO (or other inhaled pulmonary vasodilator therapy) at the time of ICU admission
- Significant lower airways obstruction (examination of ventilator and capnography waveforms by site study or medical team)
- Air leak >20% (endotracheal tube, tracheostomy tube, or thoracostomy tube)
- Home Invasive Mechanical Ventilation
- Cyanotic Congenital Heart Disease
- Previous enrollment in the DiNO study
- Do not resuscitate order at the time of pediatric ARDS diagnosis.
- Blood gas not obtained prior to initiation of ECMO, iNO, or non-conventional ventilation.

Conditions & Interventions

Conditions:

Acute Respiratory Distress Syndrome

Keywords:

Pediatrics, Mechanical Ventilation, Inhaled Nitric Oxide

More Information

Description:

The goal of this observational study is to determine whether a marker of dead space (the end-tidal to alveolar dead space fraction $\backslash[AVDSf\backslash]$) is more strongly associated with mortality risk than markers of oxygenation abnormality (oxygenation index) and to determine whether dead space (AVDSf) is an important marker of heterogeneity in the inhaled nitric oxide (iNO) treatment effect for children with acute respiratory distress syndrome (ARDS). The study aims are: 1. To validate AVDSf for risk stratification of mortality in pediatric ARDS 2. To determine if there is heterogeneity in treatment effect for iNO defined by AVDSf 3. To detect the association between AVDSf and microvascular dysfunction trajectory and whether iNO therapy modifies this association This is a prospective, multicenter observational study of 1260 mechanically ventilated children with moderate to severe ARDS. In a subgroup of 450 children with severe ARDS, longitudinal blood samples will be obtained to measure plasma protein markers.

Contact(s): Abigayle Gibson - Abigayle.Gibson@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase:

IRB Number:

System ID: NCT06690801

Thank you for choosing StudyFinder. Please visit <http://studyfinder.cchmc.org> to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.