PK, Safety and Preliminary Efficacy Study of Montelukast in Critically Ill Infants With Developing Bronchopulmonary Dysplasia

NCT07101640

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Duke University
Enrollment	28 participants

Key Eligibility Criteria

Inclusion (5)

- Documented informed consent from parent or guardian, prior to study activities
- Receiving mechanical ventilation \[high frequency or conventional\] and requiring supplemental oxygen (FiO2 e 30%) at time of randomization
- \<28 weeks' gestational age and \<1000 g bodyweight at birth
- to 28 (inclusive) days postnatal age at the time of first study drug dose
- Able to tolerate 5 mL of enteral volume

Exclusion (7)

- Previous enrollment and dosing in the current PRISM study (NICHD-2023-MON01)
- Previous exposure to montelukast within 7 days prior to randomization
- Known allergy to montelukast
- PI deems infant - prior to enrollment - is not expected to survive
- Has a disease complication that would preclude safe participation of the participant

... and 2 more (see full listing online)

Locations (4 total)

Arkansas Children's Hospital, Little Rock, Arkansas, United States
University Medical Center of Southern Nevada, Las Vegas, Nevada, United States
University of North Carolina (UNC), Chapel Hill, North Carolina, United States
... and 1 more locations