

Cool Prime Comparative Effectiveness Study for Mild HIE

NCT04621279

Status	RECRUITING
Sponsor	University of Texas Southwestern Medical Center
Enrollment	460 participants

Key Eligibility Criteria

Inclusion (13)

- Neonates born at e 36 0/7 weeks
 - Mild Encephalopathy on neonatal neurologic exam within 6 hours after birth: defined as presence of at least 2 signs of mild, moderate, or severe encephalopathy with no more than 2 signs in the moderate or severe category.
 - Perinatal Acidosis based on at least one of the following (A or B):
 - pH d 7.00 in any cord or first infant gas (arterial, venous, or capillary) within d 60 min OR base deficit e 16 in any cord or first infant gas (arterial, venous or capillary) within d 60 min
 - If pH is between 7.01 and 7.15, OR base deficit is between 10 and 15.9 mmol/liter, OR blood gas is not available, an acute perinatal event is an additional criteria required (see below definition)
- ... and 8 more (see full listing online)

Exclusion (7)

- Gestational age at birth \< 36 0/7 weeks
 - Birth weight \< 1800gm
 - Head circumference \<30cm
 - Congenital or chromosomal anomaly associated with abnormal neurodevelopment or death
 - Moderate or Severe HIE of 3 or more moderate or severe abnormalities on COOLPRIME Sarnat exam within 6 hours of life
- ... and 2 more (see full listing online)

Locations (1 total)

University of Texas Southwestern Medical Center, Dallas, Texas, United States