

Safety of Erythropoietin and Melatonin for Very Preterm Infants With Intraventricular Hemorrhage

NCT05617833

Status	RECRUITING
Phase	Phase 1
Sponsor	Johns Hopkins University
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (4)

- Neonatal intensive care unit (NICU) inpatients born at ≥ 22 and < 32 weeks gestation (born after 22w-6/7 and before or on 31-6/7 week GA)
- sIVH within the first 21 days from birth, defined as at least unilateral grade II on head ultrasound (HUS) performed within 18 days of enrollment
- Approval of the primary neonatologist
- Appropriate caregiver to provide informed consent

Exclusion (8)

- Participation in another pharmacological intervention trial that involves multiple doses of a medication that may interact with EPO+MLT. Examples of exemptions would include single dose administration for pharmacokinetic studies of an antibiotic, a single or few doses of a new surfactant, or a single intervention to reduce pain.
- Is on jet ventilator or has not been off jet ventilator for at least 72 hours
- Has been diagnosed with or is suspected of having a congenital anomaly or genetic disorder associated with brain malformation or life expectancy < 40 weeks post menstrual age (PMA). These include but are not limited to TORCH infections associated with radiographic evidence of substantial brain injury, trisomy 13, coarctation of the aorta, and severe liver failure. TORCH infections not associated with radiographic evidence of brain malformation or treatment for presumed TORCH infection are not exclusionary.
- Is within 3 days of starting treatment for a severe clinical condition which is potentially associated with a life expectancy < 3 days. These include but are not limited to disseminated intravascular coagulation (DIC)/severe hematologic crisis, severe sepsis, Hypoxic-ischemic encephalopathy (HIE), severe brain injury
- Other clinical conditions including:
... and 3 more (see full listing online)

Locations (1 total)

Johns Hopkins Hospital, Baltimore, Maryland, United States

<https://clinicaltrials.gov/study/NCT05617833>

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