

Treatment of Neonatal Encephalopathy With Oral Sildenafil Suspension to Repair Brain Injury Secondary to Birth Asphyxia

NCT06098833

Status	RECRUITING
Phase	Phase 2
Sponsor	Pia Wintermark
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (7)

- Male and female neonates meeting the criteria for induced hypothermia:
- Gestational age ≥ 36 weeks and birth weight ≥ 1800 g;
- Evidence of fetal distress, i.e., history of an acute perinatal event, cord pH ≤ 7.0 or base deficit ≥ 4 mEq/L;
- Evidence of neonatal distress, such as an Apgar score ≤ 5 at 10 minutes, postnatal blood gas pH obtained within the first hour of life ≤ 7.0 or base deficit ≥ 16 mEq/L, or a continued need for ventilation initiated at birth and continued for at least 10 minutes;
- ... and 2 more (see full listing online)

Exclusion (5)

- Neonates with complex congenital heart disease
- Neonates with cerebral malformations
- Neonates with genetic syndrome
- Neonates with intraventricular and/or intraparenchymal hemorrhage on MRI performed on day 2 of life
- Moribund infants not expected to survive

Locations (2 total)

Montreal Children's Hospital, Montreal, Quebec, Canada
Centre Hospitalier Universitaire Sainte-Justine, Montreal, Quebec, Canada