

# Erythropoietin for Neonatal Encephalopathy in LMIC (EMBRACE Trial)

NCT05395195

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Status	RECRUITING
Phase	Phase 3
Sponsor	Imperial College London
Enrollment	504 participants

## Key Eligibility Criteria

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### Inclusion (3)

- Inborn babies born at a gestational age greater than or equal to 36 weeks, with a birth weight  $\geq 1.8$  kg
- At least one of the following: need for continued resuscitation at 5 minutes of age; 5-minute Apgar score  $< 6$ ; metabolic acidosis (pH  $< 7.0$ ; base deficit  $> 16$  mmol/L) in cord or blood gas within the first hour of birth.
- Moderate or severe neonatal encephalopathy on modified Sarnat staging performed between 1 to 6 hours after birth.

### Exclusion (8)

- Imminent death at the time of recruitment
- Babies born at home or those admitted after 6 hours of birth.
- Major life-threatening congenital malformations
- Head circumference  $< 30$  cm at birth
- Babies undergoing induced hypothermia
- ... and 3 more (see full listing online)

## Locations (10 total)

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Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh  
Dhaka Medical College, Dhaka, Bangladesh  
Aurangabad Medical College, Aurangabad, India  
... and 7 more locations