

# Cooling in Mild Encephalopathy

NCT05889507

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Status	RECRUITING
Phase	Phase 3
Sponsor	Imperial College London
Enrollment	426 participants

## Key Eligibility Criteria

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### Inclusion (5)

- All babies born at or after 36 weeks of gestation with a birth weight of 1800g or more with birth acidosis or requiring resuscitation at birth will be screened for eligibility.
- Parents will be approached for consent if the baby meets all the three (A + B + C) criteria below:
- A. Evidence of intra-partum hypoxia-ischemia defined as any of - (i) Apgar score of  $\leq 6$  at 10 minutes after birth; (ii) continued need for resuscitation, including endotracheal or mask ventilation, at 10 minutes after birth; (iii) severe birth acidosis defined as any occurrence of  $\text{pH} \leq 7.00$  or a Base deficit  $\geq 16 \text{mmol/l}$  in any cord or baby gas sample within 60 minutes of birth.
- B. Evidence of mild hypoxic ischaemic encephalopathy defined as - two or more abnormal findings in any of the six categories of the modified Sarnat examination (level of consciousness, spontaneous activity, posture, tone, primitive reflexes, and autonomic nervous system) but not meeting the diagnosis of moderate or severe hypoxic ischaemic encephalopathy on a standardised examination performed by a certified examiner between 1 to 6 hours of age.
- C. Normal amplitude on aEEG performed for at least 30 minutes between 1 to 6 hours of age. Normal amplitude will be defined as upper margin of the aEEG activity more than 10 microvolts and the lower margin more than 5 microvolts on a single channel aEEG.

### Exclusion (5)

- Infants who meet the BAPM criteria for whole-body hypothermia
- Infants without encephalopathy defined as less than two abnormalities on structured neurological examination.
- Infants with major congenital or chromosomal anomalies identified prior to randomisation.
- Infants with birthweight  $\leq 1800 \text{g}$ .
- Infants who have already received sedation, muscle relaxation, or anti-convulsants prior to neurological assessment.

## Locations (39 total)

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Neonatal Unit, Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy  
William Harvey Hospital, Ashford, United Kingdom  
St Peters Hospital, Ashford, United Kingdom  
... and 36 more locations

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<https://clinicaltrials.gov/study/NCT05889507>

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