Hypothermia for Encephalopathy in Low and Middle Income Countries (HELIX) Trial

STUDY ENROLLMENT PATHWAY

Baby admitted to the Neonatal Unit with suspected HIE

Yes

Is the equipment available for both cooling and non-cooling groups?

Yes

No

Patient cannot enroll the study if equipment is being used by other baby (both cooling machine and non-cooling rectal probe must be available)

Does the baby meet ALL of the inclusion criteria and NONE of the exclusion criteria (see Screening Tool on reverse page)

Yes

Call your Local Helix Trial Consultant to perform NICHD Neurological Examination and obtaining informed consent from Parents.

Yes

According to the NICHD criteria, does this baby have moderate or severe HIE?

Yes

Have the Parents consented for the enrollment of the baby in this trial?

Yes

Once the parents have consented for the baby to take part in the study, you can now randomise the patient (see Randomisation Help Page) and start completing the Case Report Form (CRF).

For any queries, please email helix.study@imperial.ac.uk or call +4420 3313 2473 or +919840653244
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SCREENING TOOL

**Inclusion Criteria**

- Current age < 6 hours **AND** birth-weight ≥1.8 kg **AND** gestation ≥36 weeks

  - **Yes**
  - **No**

  **Not Eligible**

- Any of the following:
  - Need for continued resuscitation at 5 minutes after birth
  - 5 minute Apgar score <6 (in babies born at hospital) or lack of cry by 5 minutes of age (for babies born at home)

  - **Yes**
  - **No**

  **Not Eligible**

**Exclusion Criteria**

- Any of the following:
  - Absent heart rate at 10 minutes of age despite adequate resuscitation
  - Major life threatening congenital malformation
  - Migrant family or parents unable or unlikely to come back at 18 months
  - Lack of parental consent

  - **Yes**

  **Not Eligible**

- Call Local Helix Consultant for NICHD assessment of severity of HIE and obtaining informed consent

**Inclusion Criteria**

- Evidence of moderate or severe HIE within 6 hours of age (NICHD Criteria) **AND** parents consented?

  - **Yes**
  - **No**

  **Not Eligible**

- Patient is eligible and can be randomised

(Please see Randomisation Instructions)

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Helix_Enrollment&Screening_V2.0_12/08/2015