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Assessing the neuro-protective effect of mild cooling in neonates receiving extra-corporeal membrane oxygenation (ECMO)

Submission date 01/08/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2005	**Overall study status** Completed	
Last Edited 17/01/2014	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Assessing the neuro-protective effect of mild cooling in neonates receiving extra-corporeal membrane oxygenation (ECMO): a randomised controlled trial

Acronym
NEST Study

Study objectives
Does cooling neonates requiring extra-corporeal membrane oxygenation (ECMO) to 34°C for the first 48 to 72 hours of their ECMO run result in improved neurodevelopmental outcome at 2 years corrected age?

Please note that as of 11/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:
Initial anticipated start date: 01/11/2005
Initial anticipated end date: 30/11/2010

Please note that as of 19/05/10 this record was updated. All updates can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 11/02/2009: Trent Multi-Centre Research Ethics Committee gave approval on the 9th June 2005 (ref: 05/MRE04/22)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fully grown newborn babies requiring help with their breathing and circulation.

Interventions
Babies receiving ECMO will be randomised to standard ECMO or ECMO with mild cooling.

As of 19/05/10 this trial is now in follow-up phase.

As of 11/07/2012 the recruitment and follow-up phases are complete and the data collected are under analysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Current information as of 19/05/10:
Cognitive score from the Bayley scales of Infant and toddler Development, 3rd edition (Bayley-III) at age of 2 years (24 - 27 months)

Initial information at time of registration:
The Mental Development Index (MDI) of the Bayley scales of the surviving children in each arm of the study at the age of 2 years (24 - 27 months)

Key secondary outcome(s)
Current information as of 19/05/10:
1. Death
2. Neurological optimality score
3. Gross and fine motor score from the Bayley-III
4. Cerebral Palsy
5. Gross motor function classification score (GMFCS)
6. Seizures requiring regular anticonvulsant treatment
7. Visual difficulties not corrected by spectacles
8. Hearing difficulties requiring aids
9. Language: expressive and receptive scores from the Bayley-III
10. Parent Report of Children's Abilities (PARCA-R)
11. Infant Characteristics Questionnaire
12. The Brief Infant-Toddler Social and Emotional Assessment (BITSEA)
13. Measure of growth: height, weight and head circumference
A child will be considered to be functioning within the normal range for age if their results are within the normal range for all Bayley scores and they have a normal neurological examination, normal vision (including with spectacles) and normal hearing (no aids).

Initial information at time of registration:
1. A structured neurological assessment
2. Parent perception of their childs health at two years of age
3. The Psychomotor Development Index (PDI) from the Bayley scales
4. Visuospatial assessment
5. The Testers rating of child behaviour

Completion date
31/05/2012

Eligibility

Key inclusion criteria
Babies recruited to the study must be the existing standard criteria for ECMO eligibility.
These include:
1. To be at least 35 weeks gestation
2. To be at least 2000 g birth weight
3. To have no uncontrolled bleeding disorder
4. To have no congenital or acquired central nervous system (CNS) disorder
5. To have undergone no more than 7 consecutive days of high pressure ventilation prior to referral for ECMO
6. To be suffering from a condition which is potentially reversible
7. To have evidence of severe cardio respiratory failure
8. Less than 29 days of age, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. All neonates referred with diaphragmatic hernia
2. All neonates receiving ECMO for post operative cardiac support

Added 19/05/10:
3. All neonates who have been cooled prior to ECMO

Date of first enrolment
03/10/2005

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Professor of Neonatal Medicine
Leicester
United Kingdom
LE1 6TP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) (ref: SP/04/004)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No
Protocol article	protocol	19/04/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes