

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/01/2014	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.npeu.ox.ac.uk/nest>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Information for females can be found at: http://www.npeu.ox.ac.uk/nest/nest_downloads/NEST_study_information_leaflet_F.pdf Information for males can be found at: http://www.npeu.ox.ac.uk/nest/nest_downloads/NEST_study_information_leaflet_M.pdf

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 measure

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)

Secondary outcome measures

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 child's 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

Overall study start date

03/10/2005

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

Age group

Neonate

Sex

Both

Target number of participants

118

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

England

United Kingdom

Study participating centre

Professor of Neonatal Medicine

Leicester

United Kingdom

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Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Trust Headquarters

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Sponsor type

Hospital/treatment centre

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_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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?
Protocol article	protocol	19/04/2010		Yes	No
Results article	results	01/11/2013		Yes	No