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Development and evaluation of a standard procedure of a cuddling process allowing parents to cuddle their babies undergoing cooling therapy

Submission date
08/04/2020

Recruitment status
No longer recruiting

Registration date
21/04/2020

Overall study status
Completed

Last Edited
08/08/2022

Condition category
Neonatal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Each year around 2100 live born babies develop brain damage due to lack of oxygen at birth. These babies have cooling therapy and intensive care for almost four days to reduce long-term disabilities. However, nearly half of cooled babies die or develop disabilities. Given this risk, parents are under extreme stress, which is made worse by the current practice of not allowing parents to cuddle their babies during cooling therapy, due to concerns of affecting the cooling process and intensive care. This practice may affect the bonding between mothers and cooled babies, which in turn could affect establishing breastfeeding. Impaired parent-infant bonding could affect their mental health and brain development of the child.
Aim: Refine a 'CoolCuddle' intervention pathway to enable parents to cuddle their babies during cooling.

Who can participate?
Newborn infants born at gestation ≥ 36 weeks undergoing whole-body cooling for hypoxic-ischemic encephalopathy

What does the study involve?
The study will include St Michael's and Southmead Hospital's neonatal units in Bristol. The 'CoolCuddle' process with babies having cooling therapy will be led by two nurses and have 2 stages.
1. For 4 parent-infant pairs, the researchers will follow a standard procedure of safely moving the baby from the open cot to parent's arms after fixing the tubes and lines attached to the baby. The researchers will have at least one cuddle episode for each infant for up to 2 hours at a time. The researchers will record whether the parents are keen to do this and collect data on breathing support, heart rate, blood pressure, oxygen levels, brain activity and temperature.
2. Based on these results, the researchers will refine 'CoolCuddle' and then test it with further 20-24 parent-infant pairs. The researchers will measure its effect on the stability of the cooling process, breathing support, heart function, brain activity.

The researchers will collect data on duration of breastfeeding, length of hospital stay, parental mood and parent-infant bonding scores to decide outcomes for future study. The researchers will develop a modified cooling therapy pathway including the “CoolCuddle”.
The researchers will invite all parents and staff to be interviewed to explore their views of ‘CoolCuddle’ at both stages to improve the process and find out what they feel about it.

What are the possible benefits and risks of participating?
Benefits: Information from this part of the study will help us to evaluate the new process of cuddling babies during cooling therapy and its safety. The study will also be useful in developing ways to promote bonding between future mothers and their babies who need cooling therapy.
Risks: The researchers do not know how the baby might tolerate the cuddle during cooling therapy. However, the baby’s medical and nursing staff will closely monitor the baby and the researchers will talk to parents all the time during the process. Completing the questionnaires and taking part in the interview will take some of the parents' time and attention.

Where is the study run from?
1. St Michael's Hospital NICU (UK)
2. Southmead Hospital NICU (UK)

When is the study starting and how long is it expected to run for?
October 2019 to April 2021

Who is funding the study?
NIHR Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Ela Chakkarapani, ela.chakkarapani@bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
257430

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CH/2018/6611/PB-PG-1217-20020, CPMS 42752, IRAS 257430

Study information

Scientific Title
Evaluation of feasibility and physiological stability of parents cuddling babies during cooling therapy for hypoxic ischaemic encephalopathy: a quantitative and qualitative study

Acronym
Coolcuddle study

Study objectives
Aims:
1. To develop the existing cuddling technique for non-cooled babies receiving intensive care into a “CoolCuddle” protocol using the physiology stability data during cuddling and qualitative data from nurses, parents and medical staff
2. To investigate whether the “CoolCuddle” protocol would maintain stable cooling therapy, respiratory, cardiovascular and neurophysiology
3. To investigate the barriers and facilitators of cuddling during cooling from parents and nurses using a qualitative approach
4. To develop a modified cooling therapy pathway with the “CoolCuddle” protocol incorporated into the pathway

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2019, Office for Research Ethics Committees Northern Ireland (ORECNI) (Customer Care & Performance Directorate Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 95361407; RECA@hscni.net), ref: 19/NI/0143
Date of amendment approval: 26/11/2019

Study design
Multi-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Neonatal hypoxic ischaemic encephalopathy

Interventions
Parents of babies undergoing therapeutic hypothermia for neonatal hypoxic-ischaemic encephalopathy as per the regional protocol will be recruited after informed consent during the cooling period to cuddle their babies during cooling therapy/rewarming and intensive care.

In stage 1, we will refine the current cuddling process used for non-cooled babies receiving intensive care by using it on four parent-infant dyads. Using the physiological monitoring data and input from nurses and parents, we will develop a standard operating procedure of cuddling process that will be investigated in stage 2.

In stage 2, 20-24 parents of babies undergoing cooling therapy and intensive care will be recruited. Each family will be offered at least one cuddle during cooling/rewarming and intensive care. Physiological monitoring will include cardiorespiratory and neurophysiological, including amplitude-integrated electroencephalography and near-infrared spectroscopy.
Participating mothers will complete the Edinburgh Postnatal Depression scale and Mother-to-infant bonding scale when the baby is 5-7 days and at 8 weeks of age.
Participating fathers will complete paternal postnatal attachment scale when the baby is 8 weeks old. Parents (up to 20) and staff (n=6) will undergo qualitative interviews.

Intervention Type
Mixed

Primary outcome measure
1. During pre, cuddle and post -cuddle period:
1.1. Rectal temperature measured using a temperature probe inserted in the rectum
1.2. Mean airway pressure measured using the ventilator and patient monitor
1.3. Fraction of inspired oxygen measured using the ventilator and patient monitor
1.4. Heart rate measured from chest electrodes
1.5. Blood pressure measured from chest electrodes
1.6. Regional cerebral oxygenation measured using near infra-red spectroscopy
1.7. Interburst interval in the aEEG measured using the interburst interval from the amplitude-integrated electroencephalogram
2. Depression measured using the Edinburgh Postnatal Depression Scale (EPDS) at 5-7 days and 8 weeks
3. Mother-infant bonding scale (MIBS) at 5-7 days and 8 weeks
4. Adverse events occurring during the cuddle events measured using patient records

Secondary outcome measures

Thematic analysis of the semi-structured interviews to explore views and experiences of parents and staff participating in the CoolCuddle

Overall study start date
01/07/2019

Completion date
01/04/2021

Eligibility

Key inclusion criteria
1. Newborn infants born at gestation ≥ 36+0 weeks
1.1. Undergoing whole-body cooling for hypoxic-ischemic encephalopathy as per the national and south west neonatal network cooling therapy pathway and their parents who consent to participate in the study
1.2. Cooling provided by a cooling device offering servo-controlled cooling using a wrap or blanket covering the whole body
1.3. Receiving intensive care and will have probes monitoring core temperature and scalp EEG electrodes, may have central or peripheral arterial or venous catheter and may have a urinary catheter
2. Parents of eligible babies

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
20-24

Total final enrolment
27

Key exclusion criteria
1. Needing fraction of inspired oxygen (FiO2) >70%
2. Receiving high-frequency oscillatory ventilation
3. Requiring a mean airway pressure > 12cm H2O
4. Receiving inhaled nitric oxide for persistent pulmonary hypertension
5. >1 chest drain inserted for pneumothorax
6. Receiving three or more inotrope infusions
7. Congenital anomalies such as hydrops fetalis and congenital diaphragmatic hernia
8. Non-English speaking parents
9. If potential participants are involved in another intervention study, an eligibility check to participate in the “CoolCuddle” study will be needed before recruitment
10. If a baby excluded during the initial screening because of criteria 1 to 6, becomes eligible

later during the cooling period due to resolution of those criteria, the baby can be screened again for participation in the study

Date of first enrolment
01/10/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Michael's Hospital NICU
University Hospitals Bristol NHS Foundation Trust
Southwell Street
Bristol
United Kingdom
BS2 8EG

Study participating centre
Southmead Hospital NICU
North Bristol NHS Trust
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Southmead Road
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The primary and secondary outcomes will be published in a peer-reviewed journal. The standard operating procedure of the cuddling process and the modified cooling pathway will be published in the neonatal network website.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. University of Bristol data repository.data.bris
Raw data that forms the results will be shared when the paper is published. Anonymised data will be available for other researchers.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.6	11/02/2020	21/04/2020	No	No
Results article	observational study results	16/12/2021	08/08/2022	Yes	No
Results article	qualitative interview results	24/03/2022	08/08/2022	Yes	No
HRA research summary			28/06/2023	No	No