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mOm Incubator Pilot Study

Submission date
10/04/2018

Recruitment status
No longer recruiting

Registration date
16/04/2018

Overall study status
Completed

Last Edited
11/09/2023

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
When a baby is admitted to the neonatal unit, they will often be nursed in an incubator. Incubator care is normally used to provide a stable temperature environment to help the baby maintain his/her temperature at a normal level, until old enough, or big enough, to regulate their own temperature and can be transferred into an open cot. The aim of this study is to compare the level of thermal care delivered to a clinically stable baby in the mOm incubator and a standard (non-humidified) incubator.

Who can participate?
Babies who are stable and clinically well, but still require incubator care, without needing extra humidification, for at least the next 48 hours

What does the study involve?
The participating babies are randomly allocated to one of two groups. In one group the baby is in a standard incubator with close (hourly) monitoring of vital signs such as temperature, and in the second group the same observations are carried out but the baby is nursed in the mOm incubator. After 24 hours, the babies change over to the other incubator. There are no extra tests needed. At the end of the 48 hours the babies are returned to normal care. The staff are also asked to complete a questionnaire to give their opinion of the use of each type of incubator.

What are the possible benefits and risks of participating?
The participating babies will be more closely observed than in standard care. The mOm incubator has been carefully designed to maintain a stable temperature environment for the baby and has been manufactured under current Good Manufacturing Practice (GMP). The clinical research team have full control and responsibility for the baby's care and can withdraw a subject from the study at any time for any reason. The risks should, therefore, be no more than for standard routine incubator care.

Where is the study run from?
Ashford and St Peter's Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2018 to August 2022

Who is funding the study?
mOm Incubators Limited (UK)

Who is the main contact?
1. Dr Peter Reynolds (public)
2. Mrs Rosalyn Archer (scientific)

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
224546

ClinicalTrials.gov (NCT)
NCT03450668

Protocol serial number
Protocol ref: mOm/2018/0, IRAS number: 224546

Study information

Scientific Title
Comparison of the mOm incubator with a standard incubator for the maintenance of thermal stability in infants in infants (≤6 kg)

Acronym
mOm01

Study objectives
The study will compare the level of thermal care delivered to a clinically stable baby in the mOm incubator and a standard (non-humidified) incubator.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/11/2018, London – Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; 0207 104 8057; nrescommittee.london-harrow@nhs.net), ref: 18/LO/1757

Study design
Multi-centre randomized controlled cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm natal hypothermia

Interventions
The study is split into two arms. One arm is where the baby is in a standard incubator, with close (hourly) monitoring of vital signs such as temperature, and the second arm is where the same observations are carried out, but this time the baby is being nursed in the mOm incubator. Pre-prepared blinded randomization codes will be used which will decide whether the first 24 hours are in the standard incubator or in the mOm incubator. After 24 hours, the baby changes over to the other incubator. There are no extra tests. At the end of the 48 hours the baby will be returned to normal care.

A target of 40 participants will be recruited to provide 36 complete sets of data since parents /legal guardians or research staff can withdraw the baby from the study at any time. Staff will

also be asked to complete a questionnaire to give their opinion of the use of each type of incubator.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Thermo-regulation ability of incubator to maintain stable core temperature of the baby over 24 hours, measured on an hourly basis

Key secondary outcome(s))
1. Baseline data such as weight, gender, temperature, GA at birth, date of birth and current age of the baby will be recorded on entry to the study
2. Hourly observations (+/- 15 minutes) will be taken throughout the following 48 hours of incubator care, and will include temperature data of the incubator, plus routine clinical observations of the baby (i.e. pulse rate, temperature, O2 saturation and respiration), plus blood pressure recorded at least once per day
3. Usability: time to clean incubator between uses, recorded after incubator used for each subject
4. Adverse events: summarized at end of study and assessed on an ongoing basis if they arise
5. Staff feedback: all staff involved in the use of the incubator for care of the baby within, set up or cleaning will complete a questionnaire and provide any further anecdotal comments they wish to make

Completion date
06/08/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/11/2021:
1. Parent/legal guardian is willing and able to give informed consent for participation in the study
2. Parent/legal guardian is aged 16 years or above
3. Participant considered clinically stable from a cardiorespiratory point of view
4. Participant requires incubator care but do not require additional humidification
5. Participant requires incubator care for at least 48 hours.
6. Participant is at least 30 weeks gestational age.
7. Participant weighs 6 kg or less

Previous inclusion criteria:
1. Parent/legal guardian is willing and able to give informed consent for participation in the study
2. Parent/legal guardian is aged 16 years or above
3. Participant considered clinically stable from a cardiorespiratory point of view

4. Participant requires incubator care but do not require additional humidification
5. Participant requires incubator care for at least 48 hours.
6. Participant is at least 30 weeks gestational age.
7. Participant is less than 8 kg in weight

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Parent/legal guardian with learning disabilities or mental illness and are considered unable to give informed consent
2. Parent/legal guardian is a prisoner or young offender
3. Parent/legal guardian is considered to have a particularly dependent relationship with the investigator(s)
4. Parent/legal guardian is deemed to belong to a vulnerable group

Date of first enrolment
01/11/2021

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ashford and St Peter's Hospital NHS Foundation Trust
United Kingdom
KT16 0RZ

Sponsor information

Organisation
mOm Incubators limited

Funder(s)

Funder type
Industry

Funder Name
mOm Incubators Limited

Results and Publications

Individual participant data (IPD) sharing plan
The data will be available from Rosalyn Mazey, or mOm Incubators Ltd, in the form of the clinical study executive summary and each individual subject can be sent a copy of their individual data collected as per the Data Protection Act. This will be available for 5 years after the end of the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other unpublished results	version 1.0	01/06/2023	11/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	23/07/2021	20/09/2021	No	No