

mOm Incubator Pilot Study

Submission date 10/04/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/09/2023	Condition category Neonatal Diseases	<input type="checkbox"/> 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

Contact name

Dr Peter Reynolds

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Type(s)

Scientific

Contact name

Mrs Rosalyn Archer

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

224546

ClinicalTrials.gov number

NCT03450668

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

05/02/2018

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

Age group

Neonate

Sex

Both

Target number of participants

40

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

England

United Kingdom

Study participating centre

Ashford and St Peter's Hospital NHS Foundation Trust

United Kingdom

KT16 0RZ

Sponsor information

Organisation

mOm Incubators limited

Sponsor details

WeWork Paddington

2 Eastbourne Terrace

London

United Kingdom

W2 6GL

Sponsor type

Industry

Website

www.momincubators.com

Funder(s)

Funder type

Industry

Funder Name

mOm Incubators Limited

Results and Publications

Publication and dissemination plan

The protocol is not published as it contains confidential information for a pre-market device. Planned publication of the results in a high-impact peer-reviewed journal if possible and presented at an international conference the intent to publish date around one year after the overall trial end date.

Intention to publish date

01/10/2023

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?
Protocol file	version 2.0	23/07/2021	20/09/2021	No	No
HRA research summary			28/06/2023	No	No
Other unpublished results		01/06/2023	11/09/2023	No	No