

# mOm Incubator Pilot Study

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

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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 ( $\leq 6$  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

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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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other unpublished results</a>	version 1.0	01/06/2023	11/09/2023	No	No
<a href="#">Protocol file</a>	version 2.0	23/07/2021	20/09/2021	No	No