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Bag and mattress or bag for preterm infants in the delivery room: The Bambino Trial

Submission date	Recruitment status	[ ] Prospectively registered
31/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/09/2013	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Should exothermic mattresses be used in combination with polyethylene bags to prevent heat loss in preterm infants at birth? (bag and mattress or bag in the delivery room): a randomised controlled trial

Acronym
The Bambino Trial

Study objectives
For newborn infants less than 31 weeks nursed in polyethylene bags under radiant heat, the use of exothermic mattresses results in more infants with admission temperatures outside the normal range (core temperature 36.5 - 37.5°C).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of The National Maternity Hospital, Dublin, approved on the 22nd December 2010

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

Health condition(s) or problem(s) studied
Prematurity/prevention of hypothermia in newborns

Interventions
Infants in both groups will be placed in a polyethylene bag and placed under radiant heat after birth. Infants randomised to the "bag" group will receive no additional measures to provide heat. Infants randomised to "mattress group" will, in addition, be placed on an exothermic chemical mattress (TransWarmer® Infant Transport Mattress, Cooper Surgical Inc., Trumbull CT, USA) which will be activated before delivery.

The primary outcome for this trial is the infant's core (rectal) temperature on admission to the neonatal intensive care unit. All infants will be followed until hospital discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Core temperature 36.5 - 37.5°C on admission to the Neonatal Intensive Care Unit (NICU)

Secondary outcome measures
1. Apgar scores at 5 and 10 minutes
2. Positive pressure ventilation (PPV) in the delivery room (DR)
3. Intubation and mechanical ventilation in the DR
4. Supplemental oxygen in the DR
5. Chest compressions in the DR
6. Use of adrenaline and volume resuscitation in the DR
7. Time to NICU admission
8. Intubation and mechanical ventilation during hospital stay
9. Duration of oxygen therapy (hours and days)
10. Oxygen therapy at 28 days
11. Oxygen therapy at 36 weeks' corrected gestational age
12. Sepsis early and late onset
13. Patent ductus arteriosus
14. Intraventricular haemorrhage
15. Periventricular leukomalacia
16. Necrotising Enterocolitis
17. Hospital days
18. Death before hospital discharge

Overall study start date
11/01/2011

Completion date
30/06/2012

Eligibility

Key inclusion criteria
Infants born at the National Maternity Hospital (NMH) at less than 31 weeks gestation by best obstetric estimate

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
116

Key exclusion criteria
Known congenital anomaly with an open lesion (e.g. gastroschisis or myelomeningocele)

Date of first enrolment
11/01/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Ireland

Study participating centre
Neonatal Intensive Care Unit
Dublin
Ireland
2

Sponsor information

Organisation
The National Children's Research Centre (Ireland)

Sponsor details
Our Lady's Children's Hospital
Crumlin
Dublin
Ireland
12

Sponsor type
Research organisation

Website
http://www.nmh.ie/iopen24/index.php

ROR

https://ror.org/025qedy81

Funder(s)

Funder type
Research organisation

Funder Name
The National Children's Research Centre (Ireland)

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?
Results article	results	01/07/2013		Yes	No