

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

Submission date 31/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/09/2013	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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
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Sponsor information

Organisation
The National Children's Research Centre (Ireland)

ROR
<https://ror.org/025qedy81>

Funder(s)

Funder type
Research organisation

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

Results and Publications

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