

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

<b>Submission date</b> 31/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/09/2013	<b>Condition category</b> 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

**Protocol serial number**  
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

**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?
<a href="#">Results article</a>	results	01/07/2013		Yes	No