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Prevention of hypothermia, in the immediate neonatal period, in infants with gestational age ≤28 weeks: a comparative study of the effectiveness of two models of polyethylene bags

Submission date	Recruitment status	[X] Prospectively registered
16/02/2016	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
19/02/2016	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
19/02/2016	Neonatal Diseases	[_] Record updated in last year

Plain English Summary

Background and study aims
Hypothermia occurs when body temperature drops below 35C (95F). One of the most effective ways to prevent hypothermia in newborn infants of extremely low birth weight is to immediately place them in a polyethylene bag, covering the trunk and limbs, covering the head with a wool cap or the bag itself. The polyethylene bags used are usually sterile bags used for packaging or organs or for preserving food, which were not originally designed for protection of the newborn. They are unadjusted for newborn containment, in particular of the head, where significant heat loss occurs. A polythene bag specifically designed for this purpose has recently been marketed, which fits easily on the body surface of the newborn, in particular the head. The aim of this study is to compare the effectiveness of two polyethylene bags for the prevention of hypothermia after birth in infants with gestational age ≤28 weeks.

Who can participate?
Newborns with gestational age ≤28 weeks

What does the study involve?
Newborns are randomly allocated to be placed either in the new bag or the usual bags. The effectiveness of the two bags at preventing hypothermia is determined by measuring the skin temperature of the newborns on admission to the neonatal intensive-care unit (NICU).

What are the possible benefits and risks of participating?
We expect that there will be less heat loss (higher skin temperature) with the new bag compared with the usual bag, leading to higher survival rates and other better outcomes. We do not expect any possible risk, as it is currently accepted practice to put preterm babies in plastic bags (face excluded) as this has been proved to be better than no bag.

Where is the study run from?
Maternidade Dr. Alfredo Da Costa and Hospital Professor Doutor Fernando Fonseca and Hospital Professor Doutor Fernando Fonseca (Portugal)

When is the study starting and how long is it expected to run for?
March 2016 to August 2018

Who is funding the study?
Vygon (Portugal)

Who is the main contact?
Dr Eduardo Fernandes

Contact information

Type(s)
Scientific

Contact name
Dr Eduardo Fernandes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevention of hypothermia, in the immediate neonatal period, in infants with gestational age ≤28 weeks: a comparative study of the effectiveness of two models of polyethylene bags

Study hypothesis

The hypothesis of the study is that it will be possible to obtain a significantly higher skin temperature (study of superiority) in newborns with Neohelp TM bag (intervention group) compared to the usual, single wall, bags (control group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Centro Hospitalar de Lisboa Central, 13/01/2016, ref: 255/2015
2. Ethics Committee of Professor Fernando Fonseca Hospital, 26/11/2015

Study design
Interventional clinical multicenter randomized prospective controlled open-label study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Condition
Prevention of hypothermia, in the immediate neonatal period, in infants with gestational age ≤28 weeks

Interventions
Informed consent will be obtained from one of the parents before birth. Randomization (1: 1) of newborns, for one of the two groups, will be performed immediately before delivery, through closed opaque envelope opening, numbered sequentially, which contains the assigned study group (intervention or control), obtained by table of random numbers generated by computer (variable block randomization for 2 to 4). Concealment of the intervention is not possible.

Newborn twins will be randomized individually. After childbirth and verifying the absence of exclusion criteria, the only difference in care between the two groups is the intervention: newborns randomized to the intervention group are placed immediately, without drying, in Neohelp TM bag and the newborns randomized to the control group are placed immediately, without drying, in the usual bags, with drying and head cover with a cap. The remaining practices, stabilization/resuscitation, transport to the Neonatal Intensive Care Unit (NICU) and routine care are determined by the usual practice of the units and will be the same in the two

groups. After admission to the NICU, removing the polyethylene bag is held after the placement of central pathways and stabilization of body temperature (36.5-37,5°C) in the incubator with 85% humidity.

The following variables will be recorded and monitored:
1. Delivery room ambient temperature (°C), immediately before the birth, with environmental pattern thermometer
2. Maternal temperature at delivery (°C)
3. Date and time of birth (hh:mm)
4. Time (hh:mm) and skin temperature (°C) of newborn in admission on the NICU, using skin temperature sensor, placed in the liver area
5. Newborn's temperature (° C) 1 hour after admission
6. Gestational age (weeks and days)
7. Birth weight (grams)
8. Sex
9. Twinning and birth order
10. Type of delivery (cesarean section or vaginal)
11. Maternal fever (> 37.5 ° C)
12. Chorioamnionitis
13. Tracheal intubation at birth
14. Need of advanced resuscitation at birth (cardiac massage, adrenaline, umbilical catheterization)
15. Worst pH and base deficit in the first 6 hours
16. Maximum O2 needed in the first 24 hours
17. Number of days of O2 supplement
18. Number of days of invasive ventilation
19. Number of days of non-invasive ventilation
20. Hypoglycemia during the first 24 hours of life (<45 mg/dl)
21. Hypotension in the first 24 hours of life (TAM <IG in weeks)
22. Patent ductus arteriosus with hemodynamic repercussion
23. Necrotizing enterocolitis (modified Bell's criteria)
24. Isolated gastrointestinal perforation
25. Hyaline membrane disease
26. Pulmonary hemorrhage
27. Pneumothorax
28. Bronchopulmonary dysplasia (need for supplemental O2 at 36 weeks of corrected age, in association with radiological characteristics changes)
29. Intraventricular hemorrhage (grade according to Volpe classification)
30. Cystic periventricular leukomalacia (De Vries classification)
31. Retinopathy of prematurity (grade according to International Classification of retinopathy of prematurity)
32. Late sepsis (with isolation in blood culture)
33. Hospital stay
34. Mortality during hospitalization
35. Cause of death (congenital anomaly, extreme prematurity, infectious, neurological, cardiopulmonary, gastrointestinal, other)

The duration of follow-up will be until hospital discharge.

Intervention Type
Device

Primary outcome measure
The effectiveness of the two polyethylene bag models in the prevention of neonatal hypothermia immediately after birth by measuring skin temperature of newborns on admission to the NICU

Secondary outcome measures
Comparison of the two groups for the following secondary variables related with hypothermia:
1. Metabolic acidosis
2. Hypotension
3. Hypoglycemia
4. Patent ductus arteriosus with hemodynamic significance
5. Necrotizing enterocolitis
6. Isolated gastrointestinal perforation
7. Respiratory distress syndrome
8. Pulmonary hemorrhage
9. Pneumothorax
10. Bronchopulmonary dysplasia
11. Intraventricular hemorrhage
12. Periventricular leukomalacia
13. Retinopathy of prematurity
14. Sepsis
15. Hospital stay
16. Mortality
17. Causes of death
Secondary outcomes will be measured until date of hospital discharge.

Overall study start date
01/03/2016

Overall study end date
31/08/2018

Eligibility

Participant inclusion criteria
1. Newborn infants with gestational age between 24 weeks and 0/7 days and 28 weeks and 0/7 days, according to the best obstetric estimate
2. Born in Dr. Alfredo da Costa Maternity and Professor Dr. Fernando Fonseca Hospital
3. With informed consent

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants

For detection of a difference in mean skin temperature of 1 ° C (36 ° C, SD 0.73) in the intervention group versus control group (study superiority unidirectional) with alpha 0.05 and a power of 0.8, we require 9 x 2 = 18 + 20% = 22 participants. For linear regression analysis, considering the adjustment to 1 or 2 covariates, we require about 72 to 80 cases (40 in each study group).

Participant exclusion criteria
1. Newborns with congenital anomalies not covered by skin (gastroschisis, myelominingocele) or with skin lesions that prevent the skin covering with polyethylene bag
2. Deceased in the delivery room

Recruitment start date
01/03/2016

Recruitment end date
28/02/2018

Locations

Countries of recruitment
Portugal

Study participating centre
Maternidade Dr. Alfredo Da Costa
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Study participating centre
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Sponsor information

Organisation
Vygon (Portugal)

Sponsor details

Parque Empresarial de Baltar/Parada, Rua F – Lote 1
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4585-013 BALTAR

Sponsor type
Industry

Website
http://www.vygon.pt/

ROR
https://ror.org/00qh1df20

Funder(s)

Funder type
Industry

Funder Name
Vygon (Portugal)

Results and Publications

Publication and dissemination plan
We intend to publish the results of the trial some months (6?) after it is finished in a large impact publication. We intend to make the data freely available, after anonymization, to other scientists, namely for meta-analysis or reviews.

Intention to publish date
28/02/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date