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Multicentre randomised controlled trial of HELP (heat loss prevention) in the delivery room

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 07/02/2019	**Condition category** Neonatal Diseases	

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
NCT00607464

Secondary identifying numbers

MCT-71137

Study information

Scientific Title
Multicentre randomised controlled trial of HELP (heat loss prevention) in the delivery room

Acronym
HeLP

Study objectives
Does polyethylene occlusive wrap applied immediately after delivery to infants born at less than 28 weeks gestation decrease all-cause mortality measured at discharge compared with the standard of care as determined by the Neonatal Resuscitation Program guidelines (i.e. drying under radiant heat)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Alberta Health Research Ethics Board (July 2004) & The Research Ethics Board of Sunnybrook & Women's College Health Sciences Centre (July 2004)

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hypothermia in premature infants

Interventions
Experimental arm: Polyethylene occlusive skin wrap applied immediately after birth and removed after the infant has been admitted to a stable thermoneutral environment
Control arm: standard care

For further information please contact Dr Vohra at the address listed below or Ms Maureen Reilly, RRT at Sunnybrook and Women's College Health Sciences Centre (maureen.reilly@sw.ca).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Death to discharge or at six months corrected gestational age

Secondary outcome measures
1. Axillary temperature upon arrival in Neonatal Intensive Care Unit (NICU)
2. Apgar scores, incidence of acidosis, hypotension, hypoglycaemia, seizures in the first 12 hours of life
3. Patent ductus arteriosus, respiratory distress, syndrome/chronic lung disease, necrotizing enterocolitis/GI perforation, Retinopathy of Prematurity, sepsis, hearing, pneumothorax, intraventricular Haemorrhage/periventricular leukomalacia, pulmonary hemorrhage all measured at 36 weeks corrected gestational age, or at time of death or discharge home
4. Death and neurosensory disability measured at 18 months corrected gestational age

Overall study start date
01/09/2004

Completion date
31/10/2008

Eligibility

Key inclusion criteria
Infants born at less than 28 weeks (aged 0 - 27 days, either sex) whose delivery is considered imminent and have consented (written) to participate in the trial. Prior to birth a firm decision to provide full resuscitative measures and intensive support must be made.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
1685

Key exclusion criteria
1. Infants born with major congenital anomalies that are not covered by skin (e.g. gastroschisis, meningomyelocele)
2. Infants whose deliveries are not attended by the neonatal team (e.g. precipitous delivery on route to the labour suite)
3. Infants born with blistering skin conditions that preclude the use of occlusive wrap

Date of first enrolment
01/09/2004

Date of final enrolment
31/10/2008

Locations

Countries of recruitment
Canada

Study participating centre
University of Alberta
Edmonton
Canada
T6G 2R7

Sponsor information

Organisation
University of Alberta and Sunnybrook and Women's College Health Sciences Centre (Canada) and The Vermont Oxford Network (USA)

Sponsor details
University of Alberta
222 Campus Tower
8625 - 112 Street NW
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Sponsor type
University/education

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-71137)

Funder Name
Stollery Children's Hospital Foundation, Edmonton, Alberta (Canada)

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?
Protocol article	protocol	01/09/2013	07/02/2019	Yes	No
Results article	results	01/02/2015	07/02/2019	Yes	No