

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

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/02/2019	<b>Condition category</b> Neonatal Diseases	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00607464

**Secondary identifying numbers**

## 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

Edmonton

Canada

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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?
<a href="#">Protocol article</a>	protocol	01/09/2013	07/02/2019	Yes	No
<a href="#">Results article</a>	results	01/02/2015	07/02/2019	Yes	No