

# An effectiveness evaluation of the Embrace Infant Warmer

<b>Submission date</b> 16/12/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/02/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/05/2017	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims

Normal body temperature is around 37C. Hypothermia occurs when body temperature drops below 35C. Babies are more prone to developing hypothermia because their bodies' ability to regulate temperature isn't fully developed. The aim of this study is to assess the effectiveness of the Embrace infant warmer at reducing hypothermia in newborns.

Who can participate?

Mothers and newborns in Karnataka, India

What does the study involve?

Areas where the warmer has been distributed are compared to areas where they are not used. Two types of data are collected: household survey data and newborn temperature measurements from hospitals. The costs associated with delivery , the readmission and referral rates of infants within 14 days after birth, and behavioural changes of health providers and mothers in response to the warmer are all measured.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Stanford University (USA)

When is the study starting and how long is it expected to run for?

March 2012 to January 2013

Who is funding the study?

1. Peery Foundation (USA)
2. Freeman Spogli Institute, Stanford University (USA)
3. Duke University (USA)

Who is the main contact?

Prof. Grant Miller

# Contact information

## Type(s)

Scientific

## Contact name

Prof Grant Miller

## Contact details

Stanford University  
117 Encina Commons  
Stanford  
United States of America  
CA 94305 2004

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

An effectiveness evaluation of the Embrace Infant Warmer: observational study of demand and effectiveness

## Study objectives

Evaluate the health impact and behavioral response to the presence of the Embrace infant warmer in rural Karnataka, India.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Observational non-randomised trial

## Primary study design

Observational

Secondary study design

Case-control study

**Study setting(s)**

Other

**Study type(s)**

Quality of life

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Maternal and child health

**Interventions**

The association between price and adoption decisions will be evaluated as well as any subsequent associations with health outcomes and medical expenditures of the Embrace Infant Warmer in rural Karnataka, India.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Diffusion of the Embrace warmer through professional/social networks
2. Responsiveness of patient demand to improvements in clinical quality
3. Responsiveness of provider effort to improvements in medical technology
4. Changes in newborn warmth practices in response to the warmer
5. Price responsiveness among maternity care providers

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/03/2012

**Completion date**

04/01/2013

**Eligibility**

**Key inclusion criteria**

1. Mothers who have given birth to children in Karnataka, India
2. Health providers in rural Karnataka

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

2550 neonates

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/03/2012

**Date of final enrolment**

04/01/2013

**Locations****Countries of recruitment**

India

United States of America

**Study participating centre**

**Stanford University**

Stanford

United States of America

CA 94305 2004

**Sponsor information****Organisation**

Stanford University (USA)

**Sponsor details**

450 Serra Mall

Stanford

United States of America

CA 94305 2004

**Sponsor type**

University/education

**Website**

<http://www.stanford.edu/>

**ROR**

<https://ror.org/00f54p054>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Peery Foundation (USA)

**Funder Name**

Freeman Spogli Institute for International Studies At Stanford University

**Alternative Name(s)**

Freeman Spogli Institute for International Studies At Stanford University, THE FREEMAN SPOGLI INSTITUTE FOR INTERNATIONAL STUDIES, The Freeman Spogli Institute for International Studies at Stanford, Freeman Spogli Institute for International Studies, Stanford University's Freeman Spogli Institute for International Studies, Stanford's Freeman Spogli Institute for International Studies, Stanford University, Freeman Spogli Institute for International Studies, Stanford University Freeman Spogli Institute for International Studies, FSI Stanford, FSISTanford, FSIIIS, FSI

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Research institutes and centers

**Location**

United States of America

**Funder Name**

Duke University

**Alternative Name(s)**

Duke, Universitas Dukiana, Brown School, Union Institute, Normal College, Trinity College, DU

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United States of America

## **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