

An effectiveness evaluation of the Embrace Infant Warmer

Submission date 16/12/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 16/02/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 26/05/2017	Condition category Other	☐ Individual participant data ☐ 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
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Stanford
United States of America
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Additional identifiers

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

Primary study design

Observational

Study design

Observational non-randomised trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration