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Investigation of the effect of swaddling upon lower respiratory infections, respiratory function, crying and sleep, thermal regulation and growth in infants 0 - 7 months in Mongolia

Submission date
14/06/2009

Recruitment status
No longer recruiting

Registration date
20/11/2009

Overall study status
Completed

Last Edited
13/03/2013

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.lshtm.ac.uk/ideu/research/ideu_research_detail.php?id=226,

Contact information

Type(s)
Scientific

Contact name
Dr Semira Manaseki-Holland

Contact details
Public Health, Epidemiology & Biostatistics
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
063468

Study information

Scientific Title
Investigation of the effect of swaddling upon lower respiratory infections, respiratory function, crying and sleep, thermal regulation and growth in infants 0 - 7 months in Mongolia: a randomised controlled trial

Study objectives
Null Hypothesis: Swaddled children do not have higher rates, or more severe cases of acute lower respiratory infection (ALRI) (compared to non-swaddled children).

Primary outcome study questions:
1. What is the effect of swaddling upon all episodes of pneumonia in Ulaanbaatar infants less than 7 months of age?
2. What is the effect of swaddling upon the severity of pneumonia in Ulaanbaatar infants less than 7 months of age?

Secondary outcome study questions:
1. What is the effect of age upon the first episode of pneumonia and the effect of age upon the relationship between swaddling and ALRI?
2. What are the effects of swaddling on oxygen saturation (SaO2) and respiratory rate (RR) in a sample of asymptomatic infants?
3. What is the effect of swaddling upon infant sleeping and infant fussing/crying?
4. What environmental temperatures are experienced by Mongolian infants in Ulaanbaatar? How do these relate to infant thermoregulation? How do traditional practices (type of housing, swaddling and bed sharing) contribute to effective thermoregulation in infants in harsh environmental conditions? Is there any evidence of a loss of thermal equilibrium in infants in winter in Ulaanbaatar?
5. What is the effect of swaddling upon the weight, height, head circumference of infants in Ulaanbaatar up to the age of 6 months?

Please note that this is the phase I study of the Swaddling and Health Research Project, phase II trial details can be found at: http://www.controlled-trials.com/ISRCTN41832812

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine (LSHTM) Ethics Committee approved on the 5th April 2001 (ref: ETH2003-04/107)
2. Ministry of Health (MOH) of Mongolia approved on the 10th July 2001 (ref: 2/1947)

Study design
Randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Infant respiratory function/thermoregulation/weight and height gain/sleep, fussing and restlessness

Interventions
All infants were recruited at birth and randomised to swaddling versus non-swaddling groups. Babies were then followed up intensely for 7 months.

Swaddling group:
The babies randomised into the swaddling group were to be swaddled in the common traditional Mongolian method as much as they felt comfortable. Traditional swaddling in Mongolia was as follows:
Swaddling was a tightly wrapping (2 adult fingers pass under the cloth) of a baby in several layers of cloth, covered by one warmer blanket from head to toe in a straight position after birth for about six months. Two or three ropes were used across a baby's body for binding to avoid unwrapping. For the first three months baby was swaddled most of the day and night with changes of the soiled cloth made every three or eight hours. After this age, practice varies with reducing hours of swaddling, but most infants were swaddled during sleep at least until 7 - 12 months. Duration and tightness of wrapping decreased with age. Furthermore as the baby grew, swaddling clothes for indoor may not have covered the head and would enclose the legs, trunk and arms up to the infant's necks, while after 6 months, in some occasions it only enclosed up to the waist. In the swaddling group, there was expected to be some variation in the swaddling period after 2 to 3 months, but it was usually expected to be more than 17 in 24 hours for those living in colder dwellings. Since the non-swaddling clothes had to be provided with alternatives to the readily available swaddling clothes and blankets, the swaddled group were given a blanket and 3 cotton sheets at the time of recruitment.

Swaddling, a cultural norm, was not a difficult infant care practice to achieve in this study. Swaddled babies would often be placed horizontal on a bed or carried, and not positioned vertically as with some cultures.

Non-swaddling group:
The non-swaddling group were instructed not to swaddle at all. The Mongolian stores did not sell the required size and warmth of clothing required to keep a newborn infant warmly clothed during the Siberian winters of Mongolia. Our recruitment pilot, in September 2000, indicated that in order to enable this alternative childcare method to be possible for the families

randomised to the non-swaddling group, the project needed to provide some alternatives. Therefore, at the time of recruitment, the project gave each family a sheepskin sleeping bag and hat, a cotton sleeping bag, 8 cotton 0 - 3 months outfits. At 4 and then 12 weeks, the non-swaddling group was given another sheepskin hat and 10 outfits of a bigger size, which would fit the babies until 6 months of age. Half the outfits were made in Mongolia and half were body-suits made in the UK and transported to Mongolia. The sleeping bags were designed in consultation with 'Grobags' company in England, who have worked closely with Professor Fleming (a collaborator with the study at Bristol University, and an international expert in infant temperature regulation and SIDS). The sleeping bags were made in Mongolia but the manufacturers applied specific requirements developed in the UK. The families were encouraged to make or buy their own additional outfits for their infants, but if they could not, the project ones given to them were supplied in a large enough number in order to allow for washing dirty outfits at the same time as wearing up to 3 layers of outfits for the cold winter.

The sleeping bags were to be used at the parent's discretion, but the sheepskin sleeping bag especially was thought to be particularly useful for the cold evenings and when going outside. A leaflet was prepared for each family to explain what outfits they should expect to receive and how to use these to clothe their baby.

Monitoring
In the non-swaddling group, it was expected that some families would not adhere to their instructions of not swaddling because of cultural pressures. To monitor compliance and obtain a measure of exposure, multiple sources of information were used:
1. A retrospective 24-hour history of swaddling/clothing: recorded by the field-workers during each 3-weekly home visit through recording the carer's descriptions of the style of dress /clothing/ swaddling and length of each during the past 24-hour within the 24-hour retrospective diaries (a kind of behaviour diary adapted to record swaddling/clothing pattern)
2. Direct observation of fieldworker during 3-weekly visits: of the dressing/clothing/ swaddling of each child and discreetly recording observations of the type of baby clothing items that each family washed and hung to dry on the day of visit (available for observation during the majority of visits)
3. Analysis of the 4-days prospective mother's diaries used for sleeping and crying/fussing outcome measure: as mother's own reported behaviour during 2 time periods
4. Unscheduled visits from a monitoring fieldworker: in order to estimate unreported non-compliance conducted for all families 1 to 3 times
5. End-study fieldworker impressions' questionnaire: of their impression about compliance in each family and the consistency and extent of accuracy of the reports from each family during each 3 months of child's life

For analysis, the first and third methods of exposure recordings above were quantifiable and were combined to reveal exposure to swaddling per child for use in per-protocol analysis. The other three methods detailed above were triangulated with the data from the diaries and concluded that over 95% of families' compliance was revealed through the 3-weekly 24-hour retrospective diaries and the 4-day prospective diaries.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
ALRI/pneumonia, identified by passive surveillance at the hospital and primary care centres. Doctors were re-trained in the relevant WHOs IMCI diagnostic criteria of ALRI and study protocols. Families were incentivised with free transport and medication to ensure better referral to study doctors in case of illness. Home visits by trained fieldworkers every 3 weeks took history of signs, symptoms and all doctor referrals or admissions and these were correlated with passive surveillance data. Infants with signs of severe to very severe pneumonia (IMCI defined) could be admitted and receive a CXR and pulse oximetry by trained study radiographers (trained by WHO expert using WHO criteria). X-ray films were assessed blind by 2 radiologist experts in WHO, Geneva, using consensus and WHO diagnostic pro-forma at the study end.

Measured throughout the study after recruitment until the end of the study (infants birth till 7 months of age, starting September 2002 until end of June 2003).

Secondary outcome measures
1. ALRI/pneumonia defined as in primary outcome measure and compared with age by completed months from birth, measured throughout the study after recruitment until the end of the study
2. Oxygen saturation and respiratory rate per minute (SaO2 and RR), measured at 9 - 10 weeks after birth
3. Sleeping and fussing/crying were defined as the overall 24-hour duration and number of bouts of crying and of sleeping and their particular measurements in night and day.
Two measurements of 2 to 24 hours were taken: Four successive typical days when infants were between 4 - 6 and 12 - 14 weeks of age.
4. Infants temperatures taken from three different body sites (abdomen, periphery and micro-environment) and compared to room temperature, measured by field workers who made visits according to a fixed, regular schedule.
5. Length or height, head circumference, or Mid Upper Arm Circumference (MUAC) in cm (to the nearest 0.5cm); and weight in grams. Infant weight and length were recorded at birth, and then the mean ages of 3, 16, 22, and 31 weeks after birth. Mid-upper arm circumference (MUAC) and head circumference were measured at 52 weeks after birth.

Overall study start date
10/09/2002

Completion date
05/07/2003

Eligibility

Key inclusion criteria
1. All babies born in the only four maternity hospitals of Ulaanbaatar (greater than 95% births were in these facilities)
2. Within 48 hours of birth if resident of Ulaanbaatar
3. Mother was well enough to discuss consent

Participant type(s)
Patient

Age group
Child

Sex
Female

Target number of participants
1250

Key exclusion criteria
1. Refusal to consent
2. Birth weight less than 2500 g
3. Less than 36 weeks gestation
4. Obvious congenital abnormalities (with clear medical consequences)
5. Need for infant intensive care treatment
6. Residence in very warm apartments (defined by the mother) since a pilot study indicated such families considered the home to be too hot for the baby to be wrapped

Date of first enrolment
10/09/2002

Date of final enrolment
05/07/2003

Locations

Countries of recruitment
England

Mongolia

United Kingdom

Study participating centre
Public Health, Epidemiology & Biostatistics
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Individual Sponsor (UK)

Sponsor details
c/o Semira Manaseki-Holland
Public Health, Epidemiology & Biostatistics

University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor type
Other

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 063468)

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?
Results article	results	01/02/2007		Yes	No
Results article	results	01/12/2010		Yes	No