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Improving newborn care and outcomes through training of traditional birth attendants in use of bag and mask resuscitation in three rural districts in Bangladesh

Submission date
27/02/2009

Recruitment status
No longer recruiting

Registration date
06/04/2009

Overall study status
Completed

Last Edited
14/02/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

Secondary identifying numbers
03PC04

Study information

Scientific Title
Improving newborn care and outcomes through training of traditional birth attendants in use of bag and mask resuscitation in three rural districts in Bangladesh: a cluster randomised controlled trial

Acronym
BADAS (Perinatal Care Project)

Study objectives
Will the training of traditional birth attendants (TBAs) in bag and mouth resuscitation improve newborn care and outcomes in three rural districts in Bangladesh?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Bangladesh Medical Research Council Ethics Committee gave approval on the 27th February 2005 (ref: BMRC/ERC/2004-2007/1132)
2. Great Ormond Street Hospital/Institute of Child Health Local Research Ethics Committee gave approval on the 14th March 2005 (ref: 03PC04)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Maternal and child health

Interventions

The TBAs in both the control and intervention areas all received a basic training package. The intention of the basic training package is for TBAs:
1. To be able to conduct clean and safe deliveries in the community
2. To be aware of danger signs during pregnancy, labour and the post-partum period
3. To increase awareness of danger signs among pregnant women and their families
4. To be prepared to act effectively in an emergency
5. To develop an emergency preparedness plan with pregnant women and their families
6. To refer women to health facilities in the case of emergencies
7. To accompany women who they refer to health facilities to provide additional support
8. To be able to resuscitate babies using mouth-to-mouth resuscitation

In addition to the basic training package the selected TBAs in the intervention areas also received a bag and mask training package. The intention of this training package is to enable TBAs to resuscitate babies who are not breathing at one minute using a bag and mask.

Refresher training is conducted for the basic and resuscitation training packages.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Newborn mortality, in particular asphyxia related deaths. Neonatal measured prospectively from 1st February 2005 until the end of the trial (31st December 2007). In the event of a stillbirth or a neonatal death, a verbal autopsy is completed, by the mother herself as well as by the health care provider (if present during delivery).

Secondary outcome measures
1. Maternal and neonatal home care practices
2. Utilisation of antenatal, delivery and postnatal services

All outcomes measured prospectively from 1st February 2005 until the end of the trial (31st December 2007).

Overall study start date
01/02/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Women who reside in one of the 18 study communities during the study period
2. Gave birth during the trial period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
20,000 women, 480 TBAs trained

Key exclusion criteria
1. Women who decline to be interviewed or reside outside the study area
2. Women residing in a Tea Estate

Date of first enrolment
01/02/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Bangladesh

England

United Kingdom

Study participating centre
University College London (UCL) Institute of Child Health
London
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Sponsor information

Organisation
University College London (UCL) Institute of Child Health (UK)

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Sponsor type
Research organisation

Website
http://www.ich.ucl.ac.uk/ich

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Saving Newborn Lives (SNL) Initiative (Bangladesh) (ref: 264)

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