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	Recruitment status	Prospectively registered
27/02/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
06/04/2009	Completed	Results
Last Edited	Condition category	Individual participant data
14/02/2020	Pregnancy and Childbirth	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 United Kingdom WC1N 1EH

Sponsor information

Organisation

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

Sponsor details

c/o Professor Anthony Costello Centre for International Health and Development 30 Guilford Street London United Kingdom WC1N 1EH +44 (0)20 7905 2883 a.costello@ich.ucl.ac.uk

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