ISRCTN97846009 https://doi.org/10.1186/ISRCTN97846009

Implementing simplified Neonatal Resuscitation Protocol - Helping Baby Breathe at Birth (HBB) - in a tertiary level hospital in Nepal for improved perinatal survival

Submission date
07/08/2012

Recruitment status
No longer recruiting

Registration date
15/08/2012

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Neonatal asphyxia is a medical condition that happens when a baby's brain and other organs do not get enough oxygen before, during or right after birth. This leads to almost a million deaths every year, which almost exclusively happen in low or middle income countries. For babies who are suffering from this lack of oxygen (hypoxia), a delay in receiving emergency care, such as resuscitation, can lead to severe disability in the child. This is a particular problem in these countries as a large number of births take place outside health facilities or without a skilled birth attendant present. In order to try to prevent disability and death, the American Academy of Paediatrics has developed an educational programme called “Helping Babies Breathe” (HBB). This training package is designed to train birth attendants in developing countries in essential skills of how to effectively treat hypoxia. The aim of this study is to find out whether an introduction of a simplified Neonatal Resuscitation Protocol (HBB) will improve the survival rate and overall outcome for babies suffering from hypoxia.

Who can participate?
Newborns delivered at Paropakar Maternity and Women's Hospital during the study period.

What does the study involve?
Birth attendants are provided with training in a simplified Neonatal Resuscitation Protocol (HBB), which is then used in the hospital. The number of neonatal deaths is counted over a six-month period when birth attendants are actively trained in the HBB practices. The results are then compared with a period of six months before the training began, and a period of three months after the active training ends.

What are the possible benefits and risks of participating?
A potential benefit of participating in the study is improved care offered by the trained health professionals. There are no potential risks of participating in the study.

Where is the study run from?
Paropakar Maternity and Women's Hospital (Nepal)

When is the study starting and how long is it expected to run for?
July 2012 to September 2013

Who is funding the study?
1. Laerdal Foundation (Norway)
2. Uppsala University (Sweden)

Who is the main contact?
Dr Ashish Kc
ashish.k.c@kbh.uu.se

Contact information

Type(s)
Scientific

Contact name
Dr Ashish KC

Contact details
Population Service International
Shree Mahalaxmi Sadan
GPO Box 21976
Mahalaxmisthan
Lagankhel
Lalitpur
Nepal
-
-
ashish.k.c@kbh.uu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Evaluating the implementation of a simplified Neonatal Resuscitation Protocol - Helping Baby Breathe at Birth (HBB) - in a tertiary level hospital in Nepal on perinatal outcome and survival using a before-after study design

Study objectives
The introduction of a simplified Neonatal Resuscitation Protocol (HBB) will significantly improve perinatal outcome and survival in the study setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Research Committee - Ministry of Health and Population in Nepal, ref: 2068-11-02BS
2. Ethical Review Board of Uppsala University, 15/08/2012, ref: 2012/267

Study design
Prospective cohort study with before and after design

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Perinatal mortality

Interventions
After a six month baseline period a simplified algorithm for neonatal resuscitation at birth - Helping Babies Breathe (HBB) will be implemented in the hospital. In order to improve the adherence of the birth attendants towards this new guideline on neonatal resuscitation a framework of quality improvement cycle will be instituted.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Perinatal mortality

Secondary outcome measures
1. Apgar score at 1, 5 and 10 minutes
2. Saturation at 5 and 10 minutes
3. Length of hospital stay
4. Performance of heatlh staff at resuscitation (time to initiation, time of effective ventiolation etc.)
5. Knowledge level and in-training performance of health staff

Overall study start date
01/07/2012

Completion date
30/09/2013

Eligibility

Key inclusion criteria
All newborns delivered at Paropakar Maternity and Women's Hospital in Kathmandu, Nepal during study period

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
28000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Nepal

Study participating centre
Population Service International
Lalitpur
Nepal
-

Sponsor information

Organisation
Uppsala University (Sweden)

Sponsor details
Department of Women's and Children's Health
University Hospital
Uppsala
Sweden
75185
+46 (0)18 471 00 00
mats.malqvist@kbh.uu.se

Sponsor type
University/education

Website
http://www.uu.se/

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
Laerdal Foundation (Norway)

Alternative Name(s)
Laerdal Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Funder Name
Uppsala Universitet

Alternative Name(s)
Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

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?
Protocol article	protocol	05/10/2012		Yes	No
Results article	results	05/07/2015		Yes	No
Results article	results	10/09/2015		Yes	No
Results article	results	31/08/2016		Yes	No
Results article	results	31/01/2018		Yes	No