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Effect of Safer Birth Bundle in improving newborn resuscitation for better newborn survival

Submission date
24/06/2018

Recruitment status
No longer recruiting

Registration date
01/08/2018

Overall study status
Completed

Last Edited
17/09/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
A huge number of newborns are dying all over the world with the biggest burden in low- and middle-income countries, with most of them dying during labour and first day of life. The global health community has been working tirelessly to address the issue with the focus shifting towards developing new interventions to help improve survival of newborns. One of the critical interventions is newborn resuscitation, Helping Babies Breathe (HBB), which is crucial in saving many newborns who do not breathe or cry at birth. It is an effective technique in low resource settings, emphasising starting bag-mask ventilation within the first minute after birth. This is a standard guideline aimed at helping health workers to improve their ventilation skills and thus help babies survive. The training program has been successful at improving performance of starting ventilation for babies within the first minutes of life. While bag-mask ventilation is important, it is also necessary that the ventilation rate is adequate, together with effective chest rise. Therefore, further improvement in the HBB training needs to be done in terms of building competency on continuous ventilation and ensuring adequacy of ventilation. There is a need to develop tools to provide reinforcement in the training of HBB for adequate and effective ventilation. This intervention will help health workers to improve their ventilation skills through real-time feedback and use of new and improved devices. There are two improvements made in the newborn resuscitation package: an upright bag for ventilating the babies, and NeoBeat, a heart rate monitor which can measure the heart rate of the babies based on the ventilation or chest rise. The aim of this study is to find out whether rapid feedback quality improvement processes using advanced resuscitation equipment will help improve the adequacy of newborn ventilation.

Who can participate?
All women who are about to deliver at the hospital are eligible to participate, given they are healthy and willing to participate. The study focuses on the newborn resuscitation for those babies who do not cry or breathe at birth. While all women will be enrolled in the study, only those women whose babies will be given bag-mask resuscitation will be included.

What does the study involve?
Health workers are provided a day of training using Upright Newborn Bag-Mask, NeoNatalie Advanced and NeoBeat. In this training, the participant ventilates a manikin (NeoNatalie Advanced), which has the size approximately equivalent to a 3 kg newborn using an Upright with PEEP Newborn Bag-Mask. A heart rate monitor (NeoBeat) is affixed to the NeoNatalie Advanced to guide the participant with the required heart rate (100-160 bpm). The participant is able to choose the level of difficulty (five difficulty levels) and ventilate accordingly. The manikin has been developed to simulate based on the level of difficulty, allowing participants to perform ventilations appropriately. After the training, the health workers are provided with the advanced neonatal resuscitation equipment (Upright Newborn Bag-Mask and NeoBeat) for resuscitation of newborns who have birth asphyxia. They are observed by an independent clinical observer as well as video filming.
A team of data collectors collects information on mortality outcomes and health worker's performance. The data collectors extract information from the records of the hospital and observe clinical practices on perinatal care in hospitals. A standardized data collection protocol is used to ensure consistency and stringency in the hospital. The data collectors track the pregnant women who come for delivery and they are given a unique identification number. The observer then observes the delivery process, with a focus on newborn resuscitation. The details of patients are retrieved from the patient chart and ward registers. The follow-up is for a maximum of five years for assessment of developmental milestones.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with taking part in the study

Where is the study run from?
The study is led by Golden Community and supported by Laerdal Global Health. It will be conducted at Pokhara Academy of Health Sciences/Western Regional Hospital in Pokhara, Nepal

When is the study starting and how long is it expected to run for?
June 2018 to November 2021 (updated 13/01/2021, previously: December 2019)

Who is funding the study?
Laerdal Global Health

Who is the main contact?
Dr Ashish KC
aaashis7@yahoo.com

Contact information

Type(s)
Public

Contact name
Dr Ashish KC

ORCID ID
https://orcid.org/0000-0002-0541-4486

Contact details

Uppsala University
Uppsala
Sweden
-
+46 (0)9841453806
aaashis7@yahoo.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
243/NHRC

Study information

Scientific Title
Effect of Low Dose Rapid Feedback (LDRF) quality improvement package for neonatal resuscitation protocol on clinical performance and birth outcomes in a tertiary hospital of Nepal: a clinical observation study

Study objectives
It is hypothesized that low dose rapid feedback quality improvement processes using advanced neonatal resuscitation equipment (Upright with PEEP Newborn Bag-Mask and NeoBeat) will help improve the adequacy of neonatal ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nepal Health Research Council ethical review committee, 29/05/2018, ref: 2833

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Resuscitation of newborn babies who do not breathe or cry at birth

Interventions

The Helping Babies Breathe (HBB) training program has been successful in improving the performance both in simulated and clinical setting on initiating the ventilation in non-breathing manikin and babies within first minutes of life. Thus, HBB program has been successful in bringing a global momentum on importance of ventilation in the Golden Minute. Evidence from several studies in high-income settings has shown that to ensure adequate and effective ventilation, maintaining the rate of ventilation at 30-50 breathes/minute and adequate chest rise is important. Therefore, further improvement in the HBB training needs to be done in terms of building the competency on continuous ventilation of babies for second minute of life at the rate of 30-50/minutes and ensuring adequacy of ventilation. There is a need to develop of tools to provide reinforcement in the trainings of HBB for adequate and effective ventilation.

Currently, Laerdal Global Health and Laerdal Medicine has had improvement in the neonatal resuscitation training for improving performance in second minutes of life with NeoNatalie Advanced and NeoBeat. There are two improvements made in the neonatal resuscitation package for clinical setting:

Upright bag and mask – an upright bag for ventilating the babies
NeoBeat – a heart rate monitor which can measure the heart rate of the babies based on the ventilation or chest rise.

These two tools are packaged as quality improvement interventions and coined as low dose rapid feedback processes. After the implementation of this package, the health workers will be provided a day of training on HBB 2.0 using Upright Newborn Bag-Mask, NeoNatalie Advanced and NeoBeat. In this training, the participant will ventilate a manikin (NeoNatalie Advanced), which has the size approximately equivalent to a 3 kg newborn using an Upright with PEEP Newborn Bag-Mask. A heart rate monitor (NeoBeat) will be affixed to the NeoNatalie Advanced to guide the participant with the required heart rate (100-160 bpm). The participant will be able to choose the level of difficulty (five difficulty levels) and ventilate accordingly. The manikin has been developed to simulate based on the level of difficulty, allowing participants to perform ventilations appropriately. After the training, the health workers will be provided with the advanced neonatal resuscitation equipment (Upright Newborn Bag-Mask and NeoBeat) for resuscitation of newborns who have birth asphyxia. They will be observed by an independent clinical observer as well as video filming done.

A before and after design will be instituted and the trial will be led by research manager. The pre-intervention period July 2017-March 2018 will be taken as baseline period. The intervention period will be April 2018-June 2019. A team of data collectors will be established to collect information on mortality outcomes and health worker's performance. The data collectors will extract information from the records of the hospital and observe clinical practices on perinatal care in hospitals. A standardized data collection protocol will be used to ensure consistency and stringency in the hospital. Pregnant women with gestational age equal to or more than 22 weeks with a foetal heart sound at admission who agree to participate in the study will be eligible for the study. The participants will be enrolled right from the admission and will be observed for the whole delivery process. The data collectors will track the pregnant women who come for delivery and they will be given a unique identification number. The observer will then observe the delivery process, with focus on neonatal resuscitation. The duration will depend on the delivery time. The details of patients will be retrieved from the patient chart and ward registers. The follow-up will be done for a maximum of five years for assessment of developmental milestones.

Intervention Type
Behavioural

Primary outcome(s)
1. Intrapartum mortality measured as intrapartum stillbirth (death within uterus at over 22 weeks of gestation or birth weight at least 500 g)
2. First-day neonatal mortality (deaths within first 24 hours of birth)

Key secondary outcome(s))
1. Early (0-6 days) in-hospital mortality
2. Late neonatal (7-27 days) in-hospital mortality
3. Admittance to Sick Newborn Care Units (SNCU) and morbidity epidemiology
4. Patient status and health workers' performance:
4.1. Resuscitation with bag and mask initiated within first minutes
4.2. Ventilation in non-breathing babies at the rate of 30-50 ventilations per minute in second minutes of life
4.3. Heart rate from the time of birth until 10 minutes of birth
4.4. Apgar score at 1, 5 and 10 minutes after birth
4.5. Time of first breath for non-breathing babies

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Babies delivered in the delivery room

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Babies of women who have antepartum stillbirth, congenital anomaly, Rh-incompatibility and multiple gestation

Date of first enrolment
01/09/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Nepal

Study participating centre
Pokhara Academy of Health Sciences (PoAHS)/Western Regional Hospital
Pokhara, Kaski
Pokhara
Nepal
33700

Sponsor information

Organisation
Laerdal Global Health

ROR
https://ror.org/03bh7xn56

Funder(s)

Funder type
Research organisation

Funder Name
Laerdal Foundation for Acute Medicine

Alternative Name(s)
Laerdal Foundation

Funding Body Type
Private sector organisation

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

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan

The trialists have a data sharing agreement developed which will need to be signed by relevant parties before gaining access to and analysis of the data. Both quantitative and qualitative data will be collected which will be shared with interested parties based on the data sharing agreement for further analysis. Written informed consent will be taken from all participants prior to enrolling them to the study. The data will be made available immediately after publication. The dataset will be available in CSPro for printed forms and app data can be accessed via server. The parties accessing the data will require ethical clearance from the relevant ethics committee prior to use and analysis of the data. Analysis will be done using statistical software. The trialists will share the data on a certain defined timeline, which is at 3 months and until 10 years after the study has completed. After that period, the data will be destroyed safely.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/12/2020	07/12/2020	Yes	No
Other publications	Secondary analysis comparing neonates who do and don't cry after birth	01/04/2023	11/04/2023	Yes	No
Other publications	A prospective, observational study nested within two quality improvement studies, REFINE (ISRCTN16741720) and SUSTAIN (ISRCTN18148368) of COVID-19 pandemic response	10/08/2020	17/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes