

Newborn resuscitation study in Pumwani, Kenya

Submission date 16/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 21/01/2008	Overall study status Completed	☐ Protocol
Last Edited 21/03/2013	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SSC Protocol No. 1045 (Revised)

Study information

Scientific Title
An operational evaluation of introducing training in newborn resuscitation for maternity ward staff at Pumwani hospital

Study objectives

The primary research question is to examine the ability of training to change health workers' practices when providing newborn resuscitation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Kenya Medical Research Institute National Ethical Review Committee on the 24th January 2006 (ref. SSC Protocol No 1045 [Revised]).

Primary study design

Interventional

Study design

Cluster-randomised trial with health workers as the unit of randomisation

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Birth asphyxia

Interventions

We intend to collect data on up to 5 resuscitation episodes for 28 health workers in the training group and more in the control group that should ensure our ability to detect a 25% absolute change in our primary outcome measure.

A list of the eligible staff will be made and 40% will be randomly selected and will comprise the early training group (i.e. intervention group). The remainder will comprise the control or late training group and will be trained after completion of data collection in the intervention group. For both intervention and control arms, we estimate that at best 3 to 5 observations could be made per health worker over a 6 to 7 weeks period.

The intervention is newborn life support (NLS) training supervised by trainers who have completed the European Resuscitation Council's Advanced Life Support Generic Instructor Course. The training will last 7 working hours and will be delivered on-site. This training comprises focused lectures aimed at understanding the modern approach to resuscitation and practical training using infant manikins to develop skills in airway opening, use of bag-valve-mask to inflate the chest and chest (cardiac) compressions. The course teaches an A (Airway), B (Breathing), C (Circulation) approach to resuscitation laying down a clear, step by step strategy for the first minutes of resuscitation for all resuscitation episodes conducted by nurse/midwives.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Proportion of resuscitation episodes in which appropriate initial resuscitation steps were practised as recommended in the NLS training (i.e., to open airway and assess breathing).

Key secondary outcome(s)

Frequency of inappropriate and potentially harmful practices (e.g., inappropriate positioning, wrong oxygen use, etc.).

Completion date

31/12/2006

Eligibility

Key inclusion criteria

All nurses/midwives (age range: 27 - 51), either sex, expected to provide delivery care and newborn resuscitation for a period of at least 3 months after the start of the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Kenya

Study participating centre

P.O. Box 43640

Nairobi

Kenya

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Sponsor information

Organisation

Laerdal Foundation of Acute Medicine (Norway)

ROR

<https://ror.org/01vacm368>

Funder(s)

Funder type

Research organisation

Funder Name

Laerdal Foundation of Acute Medicine (Norway)

Funder Name

The Wellcome Trust (UK) - Senior Research Fellowship award to Dr English (ref: 076827)

Results and Publications

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	13/02/2008		Yes	No