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Newborn resuscitation study in Pumwani, Kenya

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

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
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]).

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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).

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

Overall study start date
01/01/2006

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

Age group
Adult

Sex
Both

Target number of participants
Intervention: 32; control: 58 (total : 90)

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)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.laerdal.com

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

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?
Results article	results	13/02/2008		Yes	No