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Effectiveness of using high versus low fidelity manikins to improve the technical skills of pediatric residents in neonatal intubation

Submission date
15/02/2018

Recruitment status
No longer recruiting

Registration date
21/03/2018

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
About 10% of newborns require some assistance to begin breathing at birth, and about 1% need extensive resuscitative measures to survive. Optimal care provided during the first few minutes of life plays a major role in reducing morbidity (illness) and mortality (death). Therefore, the Accreditation Council for Graduate Medical Education (ACGME) currently mandates the completion of formal training, via the neonatal resuscitation program (NRP), by all pediatric residents. The term 'fidelity' is generally used to refer to the degree of realism of a simulation. Low-fidelity simulator (LFS) mannequins allow practitioners to demonstrate basic knowledge and technical and behavioral skills with verbal prompts from the instructors. High-fidelity simulators (HFS) provide the trainee with the cues necessary to interact with the patient as they would in the real clinical environment. However, there are few studies describing the use of HFS in teaching neonatal resuscitation. The aim of this study is to inform the supporting and financing bodies as to whether selecting a training method that is more costly (HFS) is justified by a better outcome of improving pediatric trainees' neonatal intubation skills and retention of these skills towards enhanced patient care.

Who can participate?
Pediatric residents in their first year of postgraduate training in pediatrics recruited from two hospitals (KAUH and MCH) in Jeddah, Kingdom of Saudi Arabia

What does the study involve?
Participants first receive a lecture reminding them of the basic anatomy of the neonatal airway and the steps required for intubating a newborn (inserting a breathing tube). Participants are then randomly allocated to use either high fidelity or low fidelity mannequins for the training of intubation. Participants are then evaluated on the same day of the training course on their newborn intubation skills and again 9-12 months after the training course.

What are the possible benefits and risks of participating?
Participants receive training on mannequins to improve their newborn intubation skills. There are no risks for the participants.

Where is the study run from?
King Abdulaziz University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
October 2017 to April 2018

Who is funding the study?
King Abdulaziz University (Saudi Arabia)

Who is the main contact?
Dr Heidi Al-Wassia
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
(HA-02-J-008)

Study information

Scientific Title
The effect of high versus low fidelity simulators on the acquisition and retention of technical skills necessary for neonatal intubation by pediatric residents: a randomized trial

Study objectives

Null hypothesis:
There is no difference in junior pediatric residents' technical skills needed to intubate a neonate as a function of training modality: high-fidelity or low-fidelity simulation.

Alternate hypothesis:
Training pediatric residents on high fidelity mannequins will result in improved pediatric residents' skills required to intubate a neonate compared to low fidelity mannequins.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Unit of Biomedical Ethics Research Committee, 28/12/2016, ref: 471-16

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intubation of neonates

Interventions
This is a randomized non-blinded trial where pediatric residents will be randomly allocated to either a training course to teach technical skills of intubating a newborn using a high fidelity or low fidelity mannequin simulator. For randomization, the trialists will use computer-generated random numbers. The randomization allocation cards will be placed in serially numbered, opaque, sealed envelopes. The trialists will ask all residents in King Abdul-Aziz University Hospital (KAUH) and Maternity and Children Hospital (MCH) to participate after signing a consent form.

Pediatric residents from the two centers will first be assessed at baseline using high fidelity simulator where they will manage a standardized simulated scenario of a neonate requiring intubation. After recruitment subjects will be randomly assigned to training on either a high fidelity or low fidelity simulator. A training course will be designed to improve the intubation skills of pediatric residents at KAUH and MCH using the assigned simulators. The high fidelity mannequin (SimBaby, Laerdal Medical Corporation, USA) is an advanced infant patient simulator

with realistic airway anatomy and clinical functionality. It features airway opening by appropriate maneuvers, suctioning suction motion, anatomical landmarks of oropharyngeal and nasopharyngeal airways, and chest rise and oxygen saturation. It utilizes software-based medical models, allowing the instructor to focus on interacting with learners rather than operating the simulator. The low fidelity mannequin is a standard plastic mannequin (ALS Baby, Laerdal Medical Corporation, USA) that allows passing ET tube and demonstrates chest rises in response to successful intubation. It does not, however, feature anatomical landmarks of the neonatal airway or give physiological cues such as oxygen saturation, heart rate and changes in CO2 detector color.

Intervention Type
Device

Primary outcome measure
Effectiveness of using HFS compared to LFS in improving the technical skills in intubating a neonate, measured by the successful passage of endotracheal tube beyond the vocal cord after the training course and 9-12 months after

Secondary outcome measures
1. Time taken to intubate is measured using stopwatch seconds at baseline, after the training course and 9-12 months after
2. Correct placement of the tube in a neonate is measured using a validated 13-item checklist score at baseline, after the training course and 9-12 months after

Overall study start date
01/10/2017

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Pediatric residents in their first year of postgraduate training in pediatrics recruited from two hospitals (KAUH and MCH) in Jeddah, Kingdom of Saudi Arabia
2. Both male and female residents

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
17 residents from KAUH and 20 from MCH

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
01/06/2017

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Abdulaziz University Hospital
King Abdulaziz University
PO Box 80215
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Sponsor information

Organisation
King Abdulaziz University

Sponsor details
PO Box 80200
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Sponsor type
University/education

ROR
https://ror.org/02ma4wv74

Funder(s)

Funder type
University/education

Funder Name
King Abdulaziz University

Alternative Name(s)
, L'université du Roi Abdulaziz, La Universidad Rey Abdulaziz, King Abdulaziz University of Saudi Arabia, KAU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
The results of the trial will be submitted to either neonatology journals or medical education journals as soon as they are ready for publication.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Heidi Al-Wassia (halwassia@kau.edu.sa).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/06/2022	16/08/2022	Yes	No