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Comparing the effectiveness of different training packages at preparing clinical staff to deploy mechanical chest compression devices

Submission date
06/06/2016

Recruitment status
No longer recruiting

Registration date
30/06/2016

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims:
When a patient's heart stops (cardiac arrest), they require immediate treatment with chest compressions. To deliver chest compressions, the rescuer must press forcefully on the breastbone approximately 100 times per minute, which can quickly become exhausting. Machines that can deliver chest compressions have been developed. These machines can consistently deliver high quality chest compressions and, unlike humans, do not get tired. However, fitting these machines on the patient can be difficult. It is important that doctors and nurses are trained as well as possible to help them use these devices effectively. Some studies suggest that training based on how a formula one motor racing pit-crew works may be better than standard training approaches on how to use these devices. The aim of this study is to investigate the effectiveness of this new pit-crew training method compared to standard training for giving chest compressions.

Who can participate?
NHS clinical staff who hold a resuscitation qualification.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard training. This involves an overview of the chest compression device, as well as the chance to practice using it. Those in the second group take part in the pit-crew training. This involves an overview of the device, and then learning to use task allocation to specific individuals in an attempt to make deployment of the device run as smoothly as possible. This will be taught by a trained instructor through a presentation, hands-on training, and simulation scenarios. Participants in both groups undergo a simulation scenario after training in which their skills and abilities are assessed.

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

Where is the study run from?
Birmingham Heartlands Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2015 to December 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30619

Study information

Scientific Title
A comparison of training packages for deployment of mechanical chest compression devices in clinical practice: a randomised controlled manikin trial (COMPRESS-SIM)

Acronym
COMPRESS-SIM

Study objectives
The aim of this study is to determine whether the 'pit-crew' training method' is more effective than standard training in preparing clinical cardiac arrest teams to deploy mechanical chest compression devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Warwick Biomedical and Scientific Research Ethics Sub-Committee, 19/02/2016, ref: REGO-2016-1759

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Education or Self-Management

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Specialty: Critical care, Primary sub-specialty: Critical care; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
Teams in the trial will be randomised to receive either standard training (control group) or pit-crew training (intervention group). Teams will be individually randomised in a 1:1 ratio using an internet-based electronic randomisation service. The team will be randomised once they attend for the training and the eligibility of each of the three team members has been confirmed.

Prior to attending the training session each participant will be asked to complete the online manufacturer training package for the mechanical chest compression device. The intervention period will be relatively short (training period of up to one hour, followed by simulation cardiac arrest scenario of approximately ten minutes). Following this, there will be no further trial intervention or follow-up.

Pit-crew training:
The training will commence with an overview of the mechanical device which builds on the participant's knowledge that was gained during the online review of the manufacturer training package. The pit-crew component of the training will focus on the use of task allocation to specific individuals in an attempt to optimise deployment of the device. This will be delivered through a presentation, hands-on training, and simulation scenarios. Training will be delivered by an instructor with experience in delivering resuscitation skills training.

Standard training: The training will commence with an overview of the mechanical device which builds on the participant's knowledge that was gained during the online review of the manufacturer training package. The remainder of the training intervention will consist of hands-on training and simulation scenarios. Deployment will not be formalised, as it is with the pit-crew intervention. Training will be delivered by an instructor with experience in delivering resuscitation skills training.

Intervention Type
Other

Primary outcome measure
Flow-fraction in the minute preceding the delivery of the first chest compression by the mechanical device, as measured in the testing scenario.

Secondary outcome measures
All outcome measures will be measured during the simulation testing scenario):
1. Adherence to manufacturer recommended process for device deployment, measured using the manufacturer checklist document
2. Non-technical skills, measured using the Team Emergency Assessment Measure tool
3. Chest compression quality, measured as flow-fraction, pre-shock pause, post-shock pause, and peri-shock pause. The overall duration of the arrest will be defined as the point that cardiac arrest is confirmed (on completion of 10-second breathing/ pulse check) to delivery of the final chest compression
4. Time to first mechanical chest compression, measured from time of arrival of the mechanical

chest compression device.
5. Number, duration and causes of any chest compression interruptions that exceed 5-seconds
6. Cause of any incident of delayed time to first mechanical chest compression- to be recorded if period from arrival of device to first mechanical chest compression is greater than 60-seconds

Overall study start date
01/10/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. NHS clinical staff (e.g. doctors, nurses, paramedics) that have current registration with a professional body (General Medical Council; Nursing and Midwifery Council; Health and Care Professions Council
2. Hold a current Resuscitation Council (UK) Immediate Life Support or Advanced Life Support qualification, or other equivalent resuscitation qualification
3. Provide written informed consent for participation
4. Prior to randomisation, participants must also have completed the manufacturer on-line training package on use of the device

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Staff that have an injury or disability that prevents the use or handling of the mechanical chest compression device
2. Receipt of formal training in use of the LUCAS-2 mechanical chest compression device in the last six months

Date of first enrolment
07/06/2016

Date of final enrolment
30/09/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Warwick

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-
Coventry
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned submission of study a results paper for publication in an appropriate healthcare journal.

Intention to publish date
31/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No