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Mechanical and manual chest compressions for resuscitation in in-hospital cardiac arrest

Submission date 09/01/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/01/2017	**Overall study status** Completed	
Last Edited 14/10/2020	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
A cardiac arrest is a serious medical condition where the heart suddenly stops pumping blood around the body. It can be fatal and so when someone has a cardiac arrest, immediate treatment is essential. Chest compressions are an essential treatment for cardiac arrest patients, but are often difficult for a person to deliver to a high standard (manual chest compressions). A mechanical chest compression device can be used to deliver chest compressions (mechanical chest compressions) instead of a person. Every year, 35,000 patients have a cardiac arrest in UK hospitals. However, less than one in five patients survives to leave hospital. When someone has a cardiac arrest, immediate treatment is essential. Small studies suggest using these devices may improve patient survival when used as part of treatment for cardiac arrest patients in hospital. The aim of this study is to conduct a small-scale study in order to find out if a large study looking comparing these two treatments would be feasible.

Who can participate?
Adults whose heart stops while they are in hospital.

What does the study involve?
Patients who have a cardiac arrest all receive manual (by hand) chest compressions initially. When the device arrives at the cardiac arrest, eligible patients are randomly allocated to continue receiving manual chest compressions or to switch to mechanical (delivered by a machine) chest compressions. For all participants, the allocated treatment is delivered for the duration of the cardiac arrest (usually between 20 minutes and two hours). Participants in both groups are followed up until they are discharged from hospital and again 30 days and six months later. Follow up involves the researchers reviewing medical records and participants completing questionnaires about their quality of life.

What are the possible benefits and risks of participating?
The key potential benefit associated with use of the mechanical device is the possibility of improved delivery of chest compressions. The key risk is that deployment of the device requires short pauses in chest compressions. Cardiac arrest teams deploying the device will receive special training so that they can use devices effectively.

Where is the study run from?
1. Birmingham Heartlands Hospital (UK)
2. University Hospital Coventry (UK)
3. Sandwell General Hospital (UK)
4.Warwick Hospital (UK)
5.Blackpool Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2015 to September 2019

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

Who is the main contact?
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Study website
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33216

Study information

Scientific Title
A feasibility randomised controlled trial of mechanical chest compression devices for in-hospital cardiac arrest (COMPRESS-RCT)

Acronym
COMPRESS-RCT

Study objectives
The aim of this study is to assess the feasibility of undertaking a randomised controlled effectiveness trial of mechanical chest compression devices in in-hospital cardiac arrest.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 12/09/2016, ref :16/WM/0299

Study design
Randomised; Both; Design type: Treatment, Device, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/compress-rct/public/compress-rct_participant_info_sheet_v2.0_16.11.2016_final_website_version.pdf

Health condition(s) or problem(s) studied
Specialty: Cardiovascular disease, Primary sub-specialty: Heart Failure; UKCRC code/ Disease: Cardiovascular/ Other forms of heart disease

Interventions
Participants are randomised in a 3:1 ratio to receive either mechanical chest compressions or manual chest compressions. Randomisation will be done by opening an opaque envelope that is kept with the device following confirmation of eligibility.

Participants in the mechanical chest compression arm will receive mechanical chest compressions delivered by the LUCAS-2 or LUCAS-3 device (Joliffe AB/ Physio-Control, Lund, Sweden).

Participants in the manual chest compression arm will continue to receive chest compressions delivered by a human.

The allocated treatment will be delivered for the duration of the cardiac arrest event (usually around 20-minutes, but may be up to two hours).

Participants will be followed-up to six-months and consists of review of medical records and completion of quality of life questionnaires.

Intervention Type
Other

Primary outcome measure
Current Primary outcome measure, as of 21/03/2018:
Proportion of eligible patients that are randomised during operational recruitment hours over the entire study period.

Previous Primary outcome measure:
Proportion of eligible participants randomised over the entire study period

Secondary outcome measures
Feasibility outcome measures:
1. Proportion of patients randomised outside of weekday daytime hours is assessed at the end of the study
2. Device deployment time (compression pause associated with device deployment) is assessed at the end of the study
3. Proportion of patients/consultees agreeing to ongoing study participation is assessed at the end of the study
4. Success of study blinding procedures is assessed at the end of the study
5. Proportion of patients with complete follow-up data is assessed at the end of the study
6. Proportion of patients with analysable chest compression quality data is assessed at the end of the study

Patient outcome measures:
1. Return of spontaneous circulation is assessed by reviewing patient notes 20 minutes following cardiac arrest
2. Survival is assessed by reviewing patient notes at hospital discharge, 30 days and 6 months
3. Neurological outcome is assessed using the cerebral performance category at discharge and modified rankin score at discharge and 6 months
4. Hospital/critical care length of stay is measured by reviewing patient notes at the time of discharge
5. Quality of life is measured using the EQ-5D and SF-12 at discharge and 6 months

Process outcome measure:
CPR quality (rate, depth, flow-fraction, pauses- pre-,post-, peri-shock) is assessed by reviewing defibrillator and/ or mechanical device data during cardiac arrest.

Safety outcome measure:
Device related adverse events are measured by reviewing patient notes up to the point of discharge

Overall study start date
01/10/2015

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Sustain an in-hospital cardiac arrest and resuscitation is attempted by a hospital cardiac arrest team trained in the use of the mechanical chest compression device
2. In a non-shockable rhythm (pulseless electrical activity or asystole) at the time of eligibility assessment
3. Known or believed to be aged 18 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 360; UK Sample Size: 360

Total final enrolment
127

Key exclusion criteria
1. Patient has valid do not attempt cardiopulmonary resuscitation order
2. Known or clinically apparent pregnancy
3. Cardiac arrest where use of a mechanical chest compression device is contra-indicated (e.g. following cardiac surgery, thoracic trauma, patient size)
4. Known previous study participation
5. Patient requiring use of mechanical chest compression device as part of routine clinical care
6. Patient known to be detained by Her Majesty’s Prison Service

Date of first enrolment
31/01/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Heartlands Hospital
Heart of England NHS Foundation Trust
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
University Hospital Coventry
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Sandwell General Hospital
Sandwell and West Birmingham Hospitals NHS Trust
Lyndon
West Bromwich
United Kingdom
B71 4HJ

Study participating centre
Warwick Hospital
South Warwickshire NHS Foundation Trust,
Lakin Road,
United Kingdom
CV34 5BW

Study participating centre
Blackpool Hospital
Blackpool Teaching Hospitals NHS Foundation Trust,
Whinney Heys
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Sponsor type
University/education

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 publication in a high-impact peer reviewed journal

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/08/2018	14/08/2019	Yes	No
Results article	results	01/09/2019	14/08/2019	Yes	No
Results article	results	01/09/2019	14/08/2019	Yes	No
Results article	results	01/01/2021	14/10/2020	Yes	No
HRA research summary			28/06/2023	No	No