

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

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<b>Registration date</b> 12/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/10/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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?

Dr Keith Couper

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### **Study website**

[www.warwick.ac.uk/compresstrial](http://www.warwick.ac.uk/compresstrial)

## **Contact information**

### **Type(s)**

Public

### **Contact name**

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### **Contact details**

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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](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

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**Study participating centre****Blackpool Hospital**

Blackpool Teaching Hospitals NHS Foundation Trust,  
Whinney Heys  
Blackpool  
United Kingdom  
FY3 8NR

## Sponsor information

**Organisation**

University of Warwick

**Sponsor details**

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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?
<a href="#">Protocol article</a>	protocol	30/08/2018	14/08/2019	Yes	No
<a href="#">Results article</a>	results	01/09/2019	14/08/2019	Yes	No
<a href="#">Results article</a>	results	01/09/2019	14/08/2019	Yes	No
<a href="#">Results article</a>	results	01/01/2021	14/10/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No