

# Prehospital Randomised Assessment of Mechanical compression Device In Cardiac arrest

<b>Submission date</b> 09/02/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/07/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A cardiac arrest happens when the heart stops pumping blood around the body. When people suffer a cardiac arrest out of hospital, the main treatment is cardiopulmonary resuscitation (CPR), during which the blood circulation is maintained by repeatedly compressing the chest. It has been suggested that mechanical devices may be more effective at providing chest compression than people, as they do not tire, can operate in difficult conditions such as a moving ambulance, and can provide compressions of the required depth and frequency sustained for a long period. The LUCAS device (Lund University Cardiopulmonary Assistance System) is one such machine. It was adopted by a few ambulance services in the UK several years ago but it is not yet known whether it improves survival rates. In this study we aim to find out whether using the LUCAS device to provide CPR enables more patients to survive than using standard manual chest compression.

### Who can participate?

Patients aged 18 years or over in cardiac arrest out of hospital

### What does the study involve?

Participating ambulance service vehicles are randomly allocated to either carry a LUCAS device or to not carry a LUCAS. If the vehicle carries a LUCAS it is used to provide chest compressions for all cardiac arrests where resuscitation is attempted. If the vehicle does not carry a LUCAS then standard manual chest compression is used.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Warwick Medical School Clinical Trials Unit (UK)

### When is the study starting and how long is it expected to run for?

June 2009 to August 2013

Who is funding the study?  
Health Technology Assessment Programme (UK)

Who is the main contact?  
Dr Simon Gates  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Simon Gates

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 07/37/69

## Study information

**Scientific Title**  
Cluster randomised controlled trial of the LUCAS™ mechanical chest compression device for out of hospital cardiac arrest

**Acronym**  
PaRAMeDIC

**Study objectives**  
The primary objective of this trial is to evaluate the effect on mortality up to discharge from hospital of using LUCAS™ rather than manual chest compression during resuscitation by

paramedics after out of hospital cardiac arrest. Secondary objectives of the study are to evaluate the effects of LUCAS™ on survival to 12 months, neurological outcomes of survivors and cost-effectiveness of LUCAS™.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration – submission pending as of 09/02/2009

**Study design**

Cluster randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**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**

Out of hospital cardiac arrest

**Interventions**

The unit of randomisation is the ambulance service vehicle (rapid response vehicles and ambulances).

The intervention arm will receive resuscitation according to the Resuscitation Council (UK) 27 and JRCALC Advanced Life Support Guidelines, with the exception that the LUCAS™ device will be deployed to replace standard manual chest compressions.

The control arm will receive resuscitation according to the Resuscitation Council (UK) and JRCALC Advanced Life Support Guidelines.

**Intervention Type**

Device

**Phase**

Not Applicable

**Primary outcome measure**

Survival to hospital discharge (the point at which the patient is discharged from the hospital acute care unit regardless of neurological status, outcome or destination).

### **Secondary outcome measures**

1. Survived event (sustained return of spontaneous circulation [ROSC], with spontaneous circulation until admission and transfer of care to medical staff at the receiving hospital)
2. Survival to 12 months
3. Health related quality of life at 3 and 12 months (SF-12® Health Survey and Euroqol EQ-5D)
4. Neurological outcome at discharge from hospital, assessed by the Cerebral Performance Category (CPC) score 1-2 v 3-5
5. Neurological outcome at 12 months, assessed by the telephone version of Mini Mental State Examination (T3MS)
6. Anxiety and depression at 12 months, assessed by the Hospital Anxiety and Depression Scale (HADS)
7. Post-traumatic stress at 12 months, assessed by the post-traumatic stress disorder (PTSD) civilian checklist (PCL-C)
8. Hospital length of stay
9. Intensive care length of stay

### **Overall study start date**

01/06/2009

### **Completion date**

31/08/2013

## **Eligibility**

### **Key inclusion criteria**

1. Patients (both males and females) in cardiac arrest in the out of hospital environment
2. Resuscitation attempt is initiated by the attending paramedic, according to Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines
3. Patient is 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**

4,200

### **Key exclusion criteria**

1. Traumatic cardiac arrest
2. Known or clinically apparent pregnancy

**Date of first enrolment**

01/06/2009

**Date of final enrolment**

31/08/2013

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Warwick Medical School Clinical Trials Unit

Coventry

United Kingdom

CV4 7AL

## Sponsor information

**Organisation**

University of Warwick (UK)

**Sponsor details**

Research Support Services

University House

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**Sponsor type**

University/education

**Website**

<http://www2.warwick.ac.uk/>

**ROR**

<https://ror.org/01a77tt86>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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?
<a href="#">Protocol article</a>	protocol	05/11/2010		Yes	No
<a href="#">Results article</a>	results	14/03/2015		Yes	No
<a href="#">Results article</a>	results	01/08/2016		Yes	No
<a href="#">Results article</a>	results	01/03/2017		Yes	No
<a href="#">Other publications</a>	post-admission outcomes	01/09/2017		Yes	No
<a href="#">Results article</a>	results	28/07/2018		Yes	No

