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Prehospital Randomised Assessment of Mechanical compression Device In Cardiac arrest

Submission date
09/02/2009

Recruitment status
No longer recruiting

Registration date
10/02/2009

Overall study status
Completed

Last Edited
30/07/2018

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Warwick Medical School Clinical Trials Unit
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (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, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/03/2015		Yes	No
Results article	results	01/08/2016		Yes	No
	results				

Results article		01/03/2017		Yes	No
Results article	results	28/07/2018		Yes	No
Protocol article	protocol	05/11/2010		Yes	No
Other publications	post-admission outcomes	01/09/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes