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What is the best shock energy for out-of-hospital cardiac arrest?

Submission date
26/01/2021

Recruitment status
No longer recruiting

Registration date
23/06/2021

Overall study status
Completed

Last Edited
18/11/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Each year, the UK ambulance services attempt to restart the hearts of 30,000 people who have suffered cardiac arrest (when the heart stops beating). Currently, less than 10% of people survive. Performance of good chest compressions (CPR) and, where appropriate, delivery of an electric shock to the heart (defibrillation) are the only proven methods of reviving these patients. Defibrillators (electric shock machines) can deliver a range of shock strengths (low, medium or high). Because we don't currently know the best shock strength to deliver, there is variation between UK ambulance services. If we can find the best shock energy levels, we can restart hearts more quickly and save more lives.
POSED is a feasibility study that will help researchers to make good decisions about a full-scale trial to make sure that time and money would be well spent.

Who can participate?
Patients who have been treated for cardiac arrest

What does the study involve?
Patients are put into different groups to receive different shock strategies. All of these shock strengths are currently used in UK ambulance services. All surviving patients will be invited to take part in the follow up which happens 30 days after the cardiac arrest. This will involve a research paramedic scoring how well they have recovered either by talking with the patient or by reading their medical notes.

What are the possible benefits and risks of participating?
Since all of the shock strategies are currently used by NHS Ambulance services it is not thought that being in the study presents any additional risk. It is not known whether any of the strategies may be better than the others. Although meeting with the Research Paramedic will take time, participants and their families may find it useful to be able to ask questions about the resuscitation process. Some may find this difficult or upsetting to talk about, but Research Paramedics are experienced in providing support and guidance to people in this situation. The relatives of non-survivors, who receive a letter telling them that their relative was in the study,

may find this causes additional emotional burden at an already difficult time. We have taken advice from many experts, patients and members of the public about the best way to word the letter and the best time to send it.

Where is the study run from?
Warwick Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
May 2019 to February 2023

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

Who is the main contact?
Ms Jes Rai, POSED@warwick.ac.uk
Prof. Gavin Perkins, cturesources@warwick.ac.uk
Mrs Helen Pocock, helen.pocock@warwick.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Prof Gavin Perkins

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
277693

Protocol serial number
CPMS 47559, IRAS 277693

Study information

Scientific Title
A feasibility study of Prehospital Optimal Shock Energy for Defibrillation (POSED)

Acronym
POSED

Study objectives
Is it feasible to conduct a randomised, pragmatic clinical effectiveness trial to identify the optimal energy for defibrillation?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/01/2021, London Harrow REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8098; harrow.rec@hra.nhs.uk), REC ref: 20/LO/1242

Study design
Interventional randomized controlled feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiac arrest

Interventions
Current intervention as of 08/01/2024 to 11/07/2022:
This study will involve putting defibrillators into one of three groups to deliver one of the three different shock strategies in current UK use. All other treatments and care will be given in the usual way. The three groups will treat the same number of patients (30 each). To try to make sure the groups are the same to start with, each defibrillator will be put into a group by chance (randomly).

Whether patients receive the shock strategy requested, what other care the patient received and whether the patients survive to hospital discharge and to 30 days will be collected for the three groups. It is possible to collect this data without the patient having to do anything, as long as the patient does not object to us collecting this data from their medical notes. By looking at ambulance service 999 call records the number of patients that could have been included will be compared to the actual number included to find the ‘recruitment rate’.

All patients who survive the cardiac arrest will be contacted by the Research Paramedic in hospital once they are on the ward and the initial emergency has passed. The Research Paramedic will explain the trial and that the patient has been included. The Research Paramedic will give the patient an information sheet to read. When the patient has had time to read the sheet the Research Paramedic will answer any questions and check with the patient if they are happy for us to continue to collect data and take part in the follow up. If someone does not have the mental capacity to consent, the Research Paramedic will inform their next of kin, known as the personal consultee, and ask if they think that the patient would be happy to take part.
All surviving patients will be invited to take part in the follow up which happens at hospital discharge and at 30 days after the cardiac arrest. This will involve a research paramedic scoring how well they have recovered either by talking with the patient or by reading their medical notes.
Members of the public have helped us to decide how we should let patients and their relatives know that they have been included in the study. Sadly, most of the patients in the study will not survive. We were not sure how to let the relatives of these patients know that they were included in the study. Members of the public told us that we should write a letter. They have helped to design these letters so that they are easy for patients and relatives to understand.

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I will also speak to the ambulance staff involved to find out what makes it easier or more difficult to record what happens to patients after treatment. Where I find difficulties, I will try to work out how I can reduce these difficulties so that a large study will work.

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Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Defibrillator

Primary outcome(s)
Current primary outcome measure as of 08/01/2024 to 21/07/2023:
Recruitment rate calculated from the number of eligible participants and the number recruited by the end of the study

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Previous primary outcome measure as of 21/07/2023:
Recruitment rate calculated from the number of eligible participants and the number recruited in the study by 24 months

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Previous primary outcome measure:
Recruitment rate recorded as the number of eligible participants enrolled in the study by 24 months

Key secondary outcome(s))

Current secondary outcome measures as of 31/07/2023:
1. Treatment adherence rate recorded as the proportion of patients receiving the allocated treatment prior to hospital admission
2. Data completeness of clinical outcomes, defined as the proportion of enrolled patients who by the end of trial have data relating to:
2.1. Return Of Organised Rhythm capable of sustaining a pulse (ROOR) assessed using defibrillator data recorded 2 min post-shock
2.2. Resulting rhythm (VF/pVT/PEA/asystole) assessed using defibrillator data recorded 2 min post-shock
2.3. Re-arrest rate (re-fibrillation) assessed using defibrillator data recorded during the out-of-hospital phase of resuscitation
2.4. Survived event (return of spontaneous circulation (ROSC)) using ambulance records at hospital handover
2.5. Survival assessed using hospital records at hospital discharge and at 30 days post cardiac arrest
2.6 Neurological outcomes (mRS score) measured using the Rankin Focused Assessment at hospital discharge and 30 days post cardiac arrest
3. Data completeness of process outcomes:
3.1. Quality of CPR (chest compression rate, chest compression depth, chest compression fraction, pre-shock pause, post-shock pause) measured using defibrillator data from the out-of-hospital phase of care
3.2. Number of shocks measured using defibrillator data from the out-of-hospital phase of care
3.3. Advanced airway applied (% advanced airway applied and % supraglottic airway or endotracheal tube) measured using patient clinical records from the out-of-hospital phase of care
3.4. Intravenous medicines administered (% cases where medicines administered and % adrenaline, amiodarone) measured using patient clinical records from the out-of-hospital phase of care
3.5. Transported to hospital (% transported) measured using Ambulance Service data from the out-of-hospital phase of care

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Previous secondary outcome measures as of 21/07/2023:
1. Treatment adherence rate recorded as the proportion of patients receiving the allocated treatment prior to hospital admission
2. Data completeness of clinical outcomes, defined as the proportion of enrolled patients who by the end of trial have data relating to:
2.1. Return Of Organised Rhythm capable of sustaining a pulse (ROOR) assessed using defibrillator data recorded 2 min post-shock
2.2. Resulting rhythm (VF/pVT/PEA/asystole) assessed using defibrillator data recorded 2 min post-shock
2.3. Re-arrest rate (re-fibrillation) assessed using defibrillator data recorded during the out-of-hospital phase of resuscitation
2.4. Survived event (return of spontaneous circulation (ROSC)) using ambulance records at hospital handover
2.5. Survival assessed using hospital records at hospital discharge and at 30 days post cardiac arrest
2.6 Neurological outcomes (mRS score) measured using the Rankin Focused Assessment at hospital discharge and 30 days post cardiac arrest

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1. Treatment adherence rate recorded as the proportion of patients receiving the allocated treatment prior to hospital admission
2. Data completeness of clinical outcomes, defined as the proportion of enrolled patients who by the end of trial have data relating to:
2.1. Neurological outcomes (mRS score) measured using the Rankin Focused Assessment at 30 days post cardiac arrest
2.2. Return Of Organised Rhythm capable of sustaining a pulse (ROOR) assessed using defibrillator data recorded 2 min post shock
2.3. Resulting rhythm (VF/pVT/PEA/asystole) assessed using defibrillator data recorded 2 min post shock
2.4. Re-arrest rate (re-fibrillation) assessed using defibrillator data recorded during the out-of-hospital phase of resuscitation
2.5. Survival assessed using hospital records at 30 days post cardiac arrest
3. Data completeness of process outcomes:
3.1. Quality of CPR (chest compression rate, chest compression depth, chest compression fraction, pre-shock pause, post-shock pause) measured using defibrillator data from the out-of-hospital phase of care
3.2. Number of shocks measured using defibrillator data from the out-of-hospital phase of care
3.3. Advanced airway applied (% advanced airway applied and % supraglottic airway or endotracheal tube) measured using patient clinical records from the out-of-hospital phase of care
3.4. Intravenous medicines administered (% cases where medicines administered and % adrenaline, amiodarone) measured using patient clinical records from the out-of-hospital phase of care
3.5. Transported to hospital (% transported) measured using Ambulance Service data from the out-of-hospital phase of care

Completion date
28/02/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/07/2023:
1. Patients suffering OHCA attended by a crew from participating ambulance service
2. Resuscitation attempted and shock delivered as per Resuscitation Council (UK) and JRCALC guidelines

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Previous inclusion criteria:
1. Patients suffering OHCA attended by a crew from participating ambulance service
2. Resuscitation attempted and shock indicated as per Resuscitation Council (UK) and JRCALC guidelines

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
38

Key exclusion criteria
Patients known or suspected to be under 18 years old

Date of first enrolment
22/03/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Central Ambulance Service NHS Foundation Trust
7-8 Talisman Road
Bicester
England
OX26 6HR

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type

Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2018-04-ST2-005

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. De-identified data underlying results reported in the article will be made available for 5 years following article publication. Proposals for data access should be directed to Prof. Gavin Perkins at cturesources@warwick.ac.uk. Investigators require approval for the use of the data by an independent review committee identified for this purpose. Requestors will need to sign a data-sharing agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/02/2024	15/03/2024	Yes	No
Results article	Process evaluation	15/10/2025	18/11/2025	Yes	No
Protocol article		06/10/2022	17/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v1.8	24/03/2021	23/06/2021	No	Yes
Protocol file	version v2.0	15/04/2021	19/07/2021	No	No
Protocol file	version 3.0	10/11/2021	11/07/2022	No	No
Protocol file	version 5.0	12/12/2022	30/01/2023	No	No
Statistical Analysis Plan	version 0.2	27/06/2022	11/07/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes