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A pilot study to investigate the use of an impedance threshold device (ITD) – the ResQPOD, to improve circulation during cardiopulmonary resuscitation (CPR) for patients in cardiac arrest

Submission date	Recruitment status	[ ] Prospectively registered
04/10/2018	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
08/11/2018	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
08/11/2018	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Sudden cardiac arrest remains an important cause of potentially avoidable early death. Overall survival rates have not significantly changed over the last 20 years in many places. There is a need to investigate potential ways of improve survival following an out of hospital cardiac arrest (OHCA). The ResQPOD Impedance Threshold Device (ITD) enhances circulation during resuscitation and has the potential to improve survival in OHCA but long-term survival has not been proven in human studies using the ITD alone. The aim of this study is to assess the feasibility of, and the requirements for, performing a larger multi-centre trial that would assess the effects of an ITD device on short- and long-term survival following OHCA.

Who can participate?

Patients aged 18 or older with an unexpected cardiac arrest attended by the North East Ambulance Service

What does the study involve?

Participants are randomly allocated to be treated with either standard care or resuscitation with the ITD. Participants are followed up using routinely collected data after 12-24 months.

What are the possible benefits and risks of participating?

Since participants will be in cardiac arrest, the benefits of taking part are potentially improved survival. Previous studies have not shown a negative effect of using an ITD. There is a theoretical risk of harm if the ITD device remains connected to the respiratory/ventilation system after ROSC system: this will be addressed during paramedic training. There are no additional risks associated with this study directly linked to the ITD.

Where is the study run from?
North East Ambulance Service NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2013 to June 2017

Who is funding the study?
Royal College of Emergency Medicine (UK)

Who is the main contact?
Dr John Wright

Contact information

Type(s)
Scientific

Contact name
Dr John Wright

Contact details
Emergency Department
Royal Victoria Infirmary
Newcastle upon Tyne NHS Hospitals Foundation Trust
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NE1 4LP

Additional identifiers

Protocol serial number
14935

Study information

Scientific Title
A pilot study to Inform a multi-centre randomised controlled trial of an impedance threshold device (ITD) – the ResQPOD, to improve survival outcomes in cardiac arrest patients (the POD pilot study)

Acronym
POD Pilot

Study objectives
Is it possible to carry out a multi-centre trial investigating whether the active impedance threshold device (ITD)-augmented cardiopulmonary resuscitation (CPR) increases survival to discharge and beyond following out-of-hospital cardiac arrest (OHCA) in comparison with no ITD-CPR?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East – Newcastle and North Tyneside 2, 10/01/2013, REC ref: 12/NE /0420

Study design
Single-centred pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Out of hospital cardiac arrest

Interventions
Intervention arm:
The Impedance Threshold Device (ITD) (ResQPODTM; ZOLL Medical Corp. and Advanced Circulatory Systems, Inc.) will be attached immediately after rhythm check and defibrillation if the presenting rhythm is ventricular fibrillation (VF) or ventricular tachycardia (VT), and immediately after the rhythm check for any other presenting rhythm, such as asystole or Pulseless Electrical Activity (PEA). Otherwise this group will receive standard cardiac arrest management administered by NHS Ambulance Trusts throughout the UK in keeping with the 2010 guidelines from the Resuscitation Council (UK). The ITD remains attached until return of spontaneous circulation (ROSC) or diagnosis of death. The follow up of survivors will be 12 months.

Control arm:
Control participants will receive treatment as usual. This group will receive standard cardiac arrest management and will be identical to the intervention group, other than not involving the ITD.

Randomisation:
Recruiting paramedics will carry one sealed trial pack each, containing a usable ITD and either a green ‘Do Use’ or red ‘Do Not Use’ randomisation card informing the paramedics whether they should or should not use the ITD. Packs will be individually numbered for tracking and will be signed out by paramedics on collection. The allocation of numbers to active (‘Do Use’) and control (‘Do Not Use’) packs will be in accordance with a pre-determined randomisation list created in Microsoft Excel. This list allowed allocation of ‘Do Use’ or ‘Do Not Use’ status to each numbered pack. All packs will be opaque and padded, and identical apart from the individual pack number and the randomisation card. Paramedics will carry one pack at a time and only open a pack when they have confirmed that a patient is in cardiac arrest and has met the study inclusion criteria. Once the pack is opened, paramedics will apply a ‘used’ sticker to seal the pack. When an ITD is used, the paramedic will collect another pack (with the lowest remaining number) at the next opportunity from a stocking station with a controlled storage area.

Intervention Type

Device

Primary outcome(s)
The pilot will assess that the study design, including if the training given to paramedics results in high rates of recruitment and whether compliance with treatment allocations is in accordance with the randomisation schedule. It will also be used to inform the sample size calculation for the larger trial and to determine likely recruitment rates. The assessment will include:
1. The correct operation of equipment and whether the control device truly results in investigator blinding, assessed using Clinical Paramedic Feedback at 0-1 weeks
2. The reliability and validity of systems of data capture for each of the likely end points of the definitive RCT, measured by cross-referencing NEAS cardiac arrest database with paramedic feedback, including electronic Patient Report Form (ePRF data) at 0-6 weeks
3. The effectiveness of systems for identifying and reporting adverse effects, measured by paramedic feedback and liaison with name hospital collaborators on outcome at 0-26 weeks
4. Endpoints for the definitive RCT, measured by assessing the outcome data in the pilot with regards to quality and access to clinical data and ease of survivor follow-up. This will occur between 12-24 months
5. Determination of the numbers required in a larger, definitive RCT and likely recruitment rates, measured using 12-month survival rates used to perform a sample size calculation. This will be performed between 12-24 months

Key secondary outcome(s))
1. Survival to discharge, collected by proforma using the Utstein criteria or routine clinical data collection through the ambulance Patient Report Forms (PRFs) at 12-24 months
2. Return of spontaneous circulation (ROSC) pre-hospital, collected by proforma using the Utstein criteria or routine clinical data collection through the ambulance Patient Report Forms (PRFs) at 12-24 months
3. Survival to Emergency Departmen, collected by proforma using the Utstein criteria or routine clinical data collection through the ambulance Patient Report Forms (PRFs) at 12-24 months
4. Survival to hospital discharge, neurologically intact, collected using the Utstein criteria or routine clinical data collection through collaboration with secondary care contacts at 12-24 months
5. 30-day and 12-month survival, neurologically intact, collected from the NHS Central Register for England and Wales at 12-24 months

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Adults aged 18 or older with an unexpected cardiorespiratory arrest
2. Primary cardiac origin was suspected, in the absence of trauma, known terminal illness or other external cause such as self-harm
3. Resuscitation attempt in accordance with normal NEAS policy

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age 17 or under
2. Do Not Attempt Resuscitation decision
3. NEAS Recognition of Life Extinct policy applied
4. ROSC prior to use of device
5. Pregnant, known or clinically suspected
6. Suspected non-cardiac origin
7. Trauma, suicide

Date of first enrolment
01/09/2013

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East Ambulance Service
North East Ambulance Service NHS Foundation Trust
Bernicia House
Goldcrest Way
Newburn Riverside
Newcastle-upon-Tyne
United Kingdom
NE15 8NY

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
University/education

Funder Name
Royal College of Emergency Medicine

Alternative Name(s)
RCEM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr John Wright (CI). All available data will be available from the November 2018 for no less than five years. Data will be anonymised quantitative Excel spreadsheet of primary and secondary variables. All appropriate requests for appropriate analysis and mechanisms will be considered. The need for participants consent has been waived following application to a REC and NIGB. All data is anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes