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Out of hospital cardiac arrest outcomes

Submission date 01/12/2014	**Recruitment status** Recruiting	[ ] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/02/2015	**Overall study status** Ongoing	
Last Edited 10/11/2023	**Condition category** Circulatory System	

Plain English Summary

Background and study aims
Cardiac arrest occurs when the heart suddenly stops pumping blood around the body. It can be caused by, for example, a heart attack, choking or trauma caused by serious injury. During a cardiac arrest, blood is no longer being circulated to vital organs and consciousness is lost within seconds. Unless steps are taken to get the heart pumping again very quickly (resuscitation), anyone suffering a cardiac arrest will die within a few minutes. In the UK, about thirty thousand people receive resuscitation treatment for a cardiac arrest that occurs outside of a hospital every year (Out of Hospital Cardiac Arrest, or OHCA). Only one in every twenty people that have a cardiac arrest survive to go home from hospital. Information collected by the Department of Health has shown there to be wide geographical variation in the number of people that survive an OHCA. In simple terms people in some parts of the country are twice or three times more likely to survive than in other areas. We want to find out the reasons why this is the case. We will develop a standardised approach to collecting information about OHCA and for finding out if a resuscitation attempt was successful. We will then use statistics to explain the reasons why survival rates vary between regions. It will provide feedback to ambulance services to allow ambulance services to learn from one another and help more patients survive a OHCA.

Who can participate?
Anyone who has had a OHCA for which resuscitation has been attempted by the ambulance service.

What does the study involve?
The study uses existing information collected by ambulance services during the course of their routine duties. Information about patients that receive resuscitation for cardiac arrest are securely transferred to researchers at the University of Warwick. The information is then used to obtain a better understanding of why survival rates vary so widely. It will work out which are the most successful treatments and it will help ambulance services improve the quality of care for victims of cardiac arrest.

What are the possible benefits and risks of participating?
Not applicable as participants are not approached directly. The project proposes to collect data already held by NHS ambulance services. Data will be extracted from existing information sources (e.g. ambulance 999 call records, ambulance clinical records, ambulance vehicle tracking systems).

Where is the study run from?
Warwick Medical School (UK)

When is the study starting and how long is it expected to run for?
October 2012 to October 2028

Who is funding the study?
1. British Heart Foundation (UK)
2. Resuscitation Council (UK)

Who is the main contact?
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Study website
http://www.warwick.ac.uk/ohcao

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OHCAO

Study information

Scientific Title
Epidemiology and Outcome from Out of Hospital Cardiac Arrest

Acronym
OHCAO

Study hypothesis
Cardiac arrest is the term used to describe sudden cessation of heart function. After cardiac arrest occurs, bloodstops being circulated to the vital organs and consciousness is lost within seconds. Unless resuscitation is started promptly death will occur within a few minutes.
Each year about 30,000 people receive resuscitation for an Out of Hospital Cardiac Arrest (OHCA) in the United Kingdom (UK). Only one in every twenty people that have a cardiac arrest survive to go home from hospital. Information collected by the Department of Health has shown there to be wide geographical variation in the number of people that survive an OHCA. In simple terms people in some parts of the country are twice or three times more likely to survive than in other areas.

The main aim of the research study is to determine the key characteristics and outcome of out of hospital cardiac arrest and explore sources of variation in outcome in the UK as a strategy to improve overall health outcomes from out of hospital cardiac arrest in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES South Central - Oxford Committee, 21/06/2013, ref: 13/SC/0361

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Community

Study type(s)
Diagnostic

Participant information sheet
The patient information sheet is not applicable as it is an observational study. We have received approval from the Confidentiality Advisory Group (CAG) to obtain patient identifiable data without consent.

Condition
Out of hospital cardiac arrest

Interventions
Current interventions as of 10/11/2023:
The aim is to provide data-driven insights to improve outcomes from cardiac arrest.

The objectives are:

1. Provide insights into cardiac arrest
2. Reduce health inequalities
3. Support high-quality research
4. Maximum collaboration
5. Facilitate data linkage

The registry will serve as a platform to establish a UK cardiac arrest research collaboration – Resuscitation Outcomes Consortium – UK.

Previous interventions as of 22/01/2019:
The aim is to collect and summarise high-quality data to support UK initiatives to improve outcomes from out of hospital cardiac arrest.
The objectives are:
1. Summarise the epidemiology, treatments and outcomes from OHCA across the UK
2. Produce reports to allow benchmarking and drive quality improvement
3. Support high-quality observational studies and randomised trials to strengthen the Chain of Survival
4. Encourage collaboration to maximise benefits from use of data submitted to OHCAO
5. Facilitate data linkage to support a better understanding of the full patient pathway for cardiac arrest (prevention, event, recovery, rehabilitation)
The registry will serve as a platform to establish a UK cardiac arrest research collaboration – Resuscitation Outcomes Consortium – UK.

Previous intervention:
To establish the epidemiology and outcome of out of hospital cardiac arrest, we will explore sources of variation in outcome and establish the feasibility of setting up a national OHCA registry.
1. To identify the optimal process for case identification and outcome verification following OHCA
2. To measure the epidemiology and outcome of out of hospital cardiac arrest in the UK
3. To determine which factors influence survival from OHCA in the UK and explore the feasibility to include in risk prediction models
4. To assess the feasibility of establishing a national OHCA registry in the UK

Intervention Type
Procedure/Surgery

Primary outcome measure
Summary data collection: For each case we will collect information from the ambulance clinical record about the time and location of the incident, information about the patient (age, sex, race) the time taken for the ambulance to arrive, the presumed cause of the cardiac arrest, the initial heart rhythm, treatments administered by bystanders and trained ambulance staff.
Main outcome measurements:
1. Initial survival (Return of spontaneous circulation i.e. restoring the heartbeat)
2. Medium – long term survival (30 days – 10 year survival). We will obtain this information from the ambulance service (initial survival) and the Medical Research Information Service (MRIS) (medium to long term survival)

Secondary outcome measures

1. The optimal process for case identification and outcome verification following OHCA
2. Factors which influence survival from OHCA in the UK and are feasible to include in risk prediction modelling
3. Feasibility of establishing a national OHCA registry in the UK

Overall study start date
01/10/2012

Overall study end date
31/10/2028

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 22/01/2019:
1. Adults and children (all ages)
2. Out-of-hospital cardiac arrest
3. Attended by or on behalf of an NHS Ambulance Service
4. Resuscitation attempted

Previous inclusion criteria:
Patients will be enrolled if after initial screening they fulfil the following criteria:
1. Out of hospital cardiac arrest
2. Resuscitation is attempted (Advanced or Basic Life Support)commenced/ continued by ambulance service

Participant type(s)
All

Age group
All

Sex
Both

Target number of participants
Approximately 30,000 eligible cases per year

Participant exclusion criteria
Current participant exclusion criteria as of 10/11/2023:
1. Cardiac arrests during inter-hospital transfer or on acute NHS hospital trust premises
2. Where there is clear evidence of death defined by the Joint Royal College Ambulance Liaison Committee (JRCALC) Recognition of life extinct (ROLE) criteria

Previous participant exclusion criteria:
1. Arrest during inter-hospital transfer or on acute NHS hospital trust premises
2. Patients with clear evidence of death defined by the Joint Royal College Ambulance Liaison Committee (JRCALC)
3. Recognition of life extinct (ROLE) criteria
Criteria for ROLE:

3.1. Massive cranial and cerebral destruction
3.2. Hemicorporectomy
3.3. Massive truncal injury incompatible with life (including decapitation)
3.4. Decomposition/putrefaction
3.5. Incineration
3.6. Hypostasis
3.7. Rigor mortis
4. A valid do not attempt resuscitation (DNAR) order or an Advanced Directive (Living Will) that states the wish of the patient not to undergo attempted resuscitation
5. When the patient's death is expected due to terminal illness
6. Efforts would be futile, as defined by the combination of all three of the following being present:
6.1. More than 15 minutes since the onset of collapse
6.2. No bystander CPR prior to arrival of the ambulance
6.3. Asystole (flat line) for >30 seconds on the ECG monitor screen. Exceptions are drowning, drug overdose/poisoning, trauma
7. Submersion of adults for longer than 1 hour

Recruitment start date
04/12/2013

Recruitment end date
31/10/2028

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Clinical Trials Unit
Division of Health Sciences
Warwick Medical School
University of Warwick
Coventry
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CV4 7AL

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
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Resuscitation Council (UK)

Results and Publications

Publication and dissemination plan
The project will measure and report health outcomes from patients following OHCA in the UK. The trialists have an established and effective dissemination strategy to ensure knowledge mobilisation is effectively integrated into practice. The personal involvement of co-investigators will facilitate opportunities for the output from this research to be widely disseminated to UK

health providers, commissioners, standard setting bodies and policy makers. The trialists will publish the results of the study in open access medical journals which will provide a sustainable archive for the results of this work. A professional and lay summary of the findings will be placed on their institutional website. They will produce briefing notes that will summarise the main findings of this research and their implications for policy and distribute these notes to health service commissioners.

2016 epidemiology report in https://warwick.ac.uk/fac/sci/med/research/ctu/trials/ohcao/publications/2015_epidemiology/anonymised_2016_final_epidemiology_report.pdf

Intention to publish date
31/10/2029

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/10/2015	23/01/2019	Yes	No
HRA research summary			28/06/2023	No	No