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Prehospital critical care for out-of-hospital cardiac arrest

Submission date
03/10/2016

Recruitment status
No longer recruiting

Registration date
12/10/2016

Overall study status
Completed

Last Edited
14/08/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Out-of-hospital cardiac arrest (OHCA, the heart of a person stops beating while they are not in a hospital) is a common problem in the developed world and survival rates remain low. The current standard of care for OHCA in most modern ambulance services is advanced life support (ALS), which involves a set of life-saving techniques designed to help keep the heart beating and a person breathing. A number of ambulance trusts in the UK send pre-hospital critical care teams (CCTs) to patients having an OHCA, in addition to ALS paramedics. CCTs can provide a similar level of care to that of an emergency department, but at the scene of illness or injury. While it seems likely that this higher level of care leads to better outcomes, research so far has not shown clear benefits from sending CCTs to OHCA. This study is made up of three parts. The aim of the first part of this study is to assess the effect of CCT care on survival from OHCA and to examine which CCT treatments are actually beneficial. The aim of the second part of this study is to analyse the costs of CCTs. The aim of the final part of this study is to find out the views of key stakeholders about prehospital research using focus groups.

Who can participate?
Adults having an OHCA can take part in the first part of the study, and members of patient and public involvement group, prehospital providers, researchers, charity staff or commissioners can take part in the final part of this study.

What does the study involve?
In this study, patients do not receive any additional treatment to what they would normally receive. All patients who suffer an OHCA are attended by paramedics trained in advanced life support (ALS). In addition, some patients also have a prehospital critical care team attending. While CCTs try to attend many cases of OHCA, this is often not possible due to distance, not being able to use the air ambulance due to bad weather or because the CCT is already attending another incident. Information about how many patients who are or are not attended by CCTs make it to hospital alive is collected, as well as how many of those patients later survive and are discharged from hospital.
The costs of CCTs are assessed by reviewing ambulance and charity financial records.

Information about the way that different people with an interest in pre-hospital care feel about research like this is collected using focus groups, which include members of the public and professionals.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to those participating in this study.

Where is the study run from?
1. South Western Ambulance Service NHS Foundation Trust (UK)
2. North East Ambulance Service NHS Trust (UK)
3. West Midlands Ambulance Service NHS Trust (UK)
4. University Hospitals Bristol NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2018

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

Who is the main contact?
Dr Johannes von Vopelius-Feldt
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
31703

Study information

Scientific Title
Prehospital critical care for out-of-hospital cardiac arrest: Mechanism, effect on survival, costs and the barriers to high quality research.

Study objectives
Prehospital critical care improves survival after out-of-hospital cardiac arrest, but at an increased cost. Stakeholders in prehospital care will have different attitudes towards the value and ethical implications of randomised research in this area.

The study aims to
1. Assess the effect of critical care team (CCT) care on survival from out-of-hospital cardiac arrest (OHCA) and to understand what interventions are delivered
2. Analyse the costs of CCTs
3. Examine barriers to high quality research in this area

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheffield National Research Ethics Service Committee, York and Humber, 29/07/2016, ref: 16/YH/0300

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cardiovascular disease, Primary sub-specialty: Arrhythmia; UKCRC code/ Disease: Cardiovascular/ Other and unspecified disorders of the circulatory system

Interventions
Observational Study of OHCA Survival:
All participating ambulance trusts collect data on OHCA which were treated by prehospital providers, for the purpose of quality assurance. This data is also forwarded to a national registry, the Out Of Hospital Cardiac Arrest Outcomes database (OHCAO), hosted at the University of Warwick. Data for this research is provided by OHCAO under a data sharing agreement and includes:
1. Ambulance trust identifying number
2. Date and time of event
3. Location of event (public place, private location or nursing home)
4. Postcode of event (district level)
5. Age-group and gender of patient
6. Do Not Attempt Resuscitation order in place

7. Suspected cause of OHCA
8. First recorded cardiac rhythm
9. Witnessed event
10. Bystander CPR
11. Public access defibrillator used by bystander
12. First EMS resource response time
13. EMS chest compressions
14. Receiving hospital (if transported to hospital)
15. Survival to hospital arrival
16. Survival to hospital discharge
In addition, the following data will be collected from CCTs when attending cases of OHCA:
1. Medical identifying number
2. Stand down prior to arrival at patient
3. CCT members: Critical care paramedic and or doctor
4. A list of critical care interventions delivered

Cost Analysis:
Data will be collected in order to estimate the costs of providing advanced life support care for OHCA in one UK ambulance trust. In addition, the additional costs incurred by providing prehospital critical care will be described. These costs will include provision of an air ambulance provided by a regional charity. The cost analysis will be stakeholder-focused and as such only consider costs occurred for prehospital care.

Qualitative Work On Research Attitudes:
Public and patients, prehospital providers, prehospital researchers, charity staff and commissioners will be contacted to participate in focus group discussions about prehosptial research lasting 60-90 minutes. The attitudes of each of these groups towards ethical issues and value of research designs, particularly randomised controlled trials will then be analysed.

Intervention Type
Other

Primary outcome(s)
Observational Study of OHCA Survival:
Survival to hospital discharge is measured by reviewing ambulance notes (in case of prehospital death) at the time of data submission by the attending prehospital provider, or through review of hospital notes of receiving hospitals (in case of survival to hospital admission) at 3 months.

Cost Analysis:
Cost of prehospital care (advanced life support and critical care) in pound sterling. Costs will be measured through review of ambulance and charity financial records.

Qualitative Work On Research Attitudes:
Themes of views about prehosptial research are assessed using information collected at focus groups.

Key secondary outcome(s))
Observational Study of OHCA Survival:
Survival to hospital admission (patient arriving in hospital with return of spontaneous circulation) is measured by reviewing ambulance notes at the time of data submission by the attending prehospital provider.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Observational Study of OHCA Survival:
1. Aged 18 years and over
2. Non-traumatic out-of-hospital cardiac arrest where cardiopulmonary resuscitation is commenced by a prehospital provider

Qualitative Work On Research Attitudes:
Member of patient and public involvement group, prehospital provider, researcher, charity staff or commissioner.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Observational Study of OHCA Survival:
1. Cardiac arrest due to trauma, asphyxia, electrocution or drowning
2. Paediatric cardiac arrest (under 18 years of age)

Date of first enrolment
01/09/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Western Ambulance Service NHS Foundation Trust
Westcountry House
Abbey Court
Eagle Way
Sowton Industrial Estate
Exeter
United Kingdom
EX2 7HY

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

Study participating centre
West Midlands Ambulance Service NHS Trust
Waterfront Business Park
Waterfront Way
Brierley Hill
United Kingdom
DY5 1LX

Study participating centre
University Hospitals Bristol NHS Foundation Trust (Qualitative Work On Research Attitudes)
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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 johannes.vonvopelius-feldt@uwe.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/07/2019	14/08/2019	Yes	No
Protocol article	protocol	07/12/2016		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes