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One hundred percent oxygen versus titrated oxygen following the return of a heartbeat after out of hospital cardiac arrest: a feasibility study

Submission date
21/11/2016

Recruitment status
No longer recruiting

Registration date
24/11/2016

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A cardiac arrest occurs when the heartbeat and breathing stop suddenly. It is one of the most extreme medical emergencies. Health outcomes are poor; less than 1 in 10 patients survive to be discharged from hospital. This study will be focusing on the stage when a patient regains a return of spontaneous circulation (ROSC), this is when the heart has started beating again after CPR by the ambulance service. Even when successfully resuscitated and admitted to the intensive care unit (ICU), only about 30% of patients survive to leave hospital. Changing the use of oxygen following the return of a heartbeat after cardiac arrest has the potential to increase survival. Previously, the maximum possible amount of oxygen has been given to patients after cardiac arrest, but it is possible that using less oxygen would improve the survival rate. Expert opinion is divided, and there is currently no research about how much oxygen should be given to patients immediately after a cardiac arrest. Traditionally, patients who have suffered cardiac arrest have been given unrestricted, 100% oxygen however some research suggests that varying the oxygen level given according to the patient's measured oxygen levels may be more effective. The aim of this study is to conduct a small study looking at the use of these two methods in order to find out if it is possible to recruit participants to a larger study.

Who can participate?
Paramedics employed full-time by South Western Ambulance Service NHS Foundation Trust (SWAST) on front-line operational duties, and who are based in Bristol or Bath and patients who have had a cardiac arrest.

What does the study involve?
Paramedics who consent to take part in the study are randomly allocated to one of the two groups. Those in the first group are asked to administer 100 percent oxygen to patients. Those in the second group are asked to administer a variable level of oxygen according to the patient's measured oxygen levels. In both groups this is maintained for one hour following the achievement of sustained ROSC. Where applicable it is continued by doctors in the Emergency

Department. Patients that survive and agree to active follow up are asked to complete questionnaires on their health related quality of life and cognitive function (mental processing) at hospital discharge and 90 days after their cardiac arrest. At the end of the study the costs of each treatment are also compared.

What are the possible benefits and risks of participating?
Paramedics will benefit from additional training in resuscitation and evidence based practice during the study. It is generally recognised that patients enrolled in research studies tend to have better outcomes than those not enrolled. It is possible that one study arm will prove to be superior to the other, but this is currently unknown. There are no notable risks involved with participating.

Where is the study run from?
1. South Western Ambulance Service NHS Foundation Trust (UK)
2. Bristol Royal Infirmary (UK)
3. Royal United Hospital Bath (UK)
4. Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2014 to October 2015

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

Who is the main contact?
Dr Sarah Voss
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
17764

Study information

Scientific Title
Cluster randomised comparison of the effectiveness of 100% oxygen versus titrated oxygen in patients with a sustained return of spontaneous circulation following out of hospital cardiac arrest: a feasibility study

Acronym
CAIRO WPC: PROXY

Study objectives
The aim of this study is to determine the feasibility of completing a cluster-randomised clinical trial to determine if titrated oxygen therapy (target SpO2 94-98%) for one hour after return of spontaneous circulation (ROSC) improves outcome (including survival and quality of life at hospital discharge and 90 days following out of hospital cardiac arrest) compared with the use of 100% oxygen in out of hospital cardiac arrest (OHCA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 23/12/2014, ref: 14/SC/1269

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Other

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Injuries and emergencies, Primary sub-specialty: Injuries and emergencies

Interventions
Paramedics employed full-time by South Western Ambulance Service NHS Foundation Trust (SWAST) on front-line operational duties, and who are based in Bristol or Bath, will be invited to participate in the study through a process of informed consent. All out of hospital cardiac arrest patients attended by a PROXY paramedic are automatically enrolled in the study. Paramedics who consent to take part in the study will be randomly allocated, to one of the two study arms.

Arm 1: Paramedics will be asked to administer either 100 percent oxygen in patients with a sustained (greater than 2 minutes) ROSC following OHCA.

Arm 2: Paramedics will be asked to administer a variable level of oxygen according to the patient's measured oxygen levels, in patients with a sustained (greater than 2 minutes) ROSC following OHCA.

The intervention will be maintained for one hour following the achievement of sustained ROSC. Where applicable the intervention will be continued by doctors in the Emergency Department. Patients that survive and agree to active follow up will be asked to complete questionnaires on their health related quality of life and cognitive function at hospital discharge and 90 days after their OHCA. At the end of the study we will compare treatment costs.

Intervention Type
Other

Primary outcome(s)
Recruitment rate is measured as the proportion of eligible paramedics attending training and consenting to take part at the end of the recruitment period.

Key secondary outcome(s)
1. Proportion of surviving participants providing quality of life data at discharge and 90 days is measured by the number of patients completing the modified Rankin Scale, EuroQol EQ-5D-5L and the SF-36 instruments at discharge and 90 days following OHCA
2. Survival to discharge and 90-days is measured by reviewing patient notes at hospital discharge and 90 days following OHCA

Completion date
31/10/2015

Eligibility

Key inclusion criteria
1. Sustained a cardiac arrest in the pre-hospital setting believed to be of a non-traumatic cause. Cardiac arrest will be defined according to the Utstein Definition as "the cessation of cardiac mechanical activity as confirmed by the absence of signs of circulation. If an EMS provider or physician did not witness the cardiac arrest, he/she may be uncertain as to whether a cardiac arrest actually occurred." For the purposes of this study, patients will be eligible for inclusion if they are attended by ambulance staff and are believed by those staff to have suffered a cardiac arrest.
2. ROSC (indicated by signs of circulation: usually a palpable central or peripheral pulse) for greater than 2 minutes (sustained ROSC) has been achieved
3. Attended by a paramedic participating in the trial
4. Known, or believed to be, 18 years of age, or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Less than 18 years old
2. Cardiac arrest believed to have been caused by trauma (including hanging and drowning)
3. Entered into the study previously
4. Detained by Her Majesty's Prison Service

Date of first enrolment
13/01/2015

Date of final enrolment
12/07/2015

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Bristol Royal Infirmary
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Royal United Hospital Bath
Combe Park

Avon
United Kingdom
BA1 3NG

Study participating centre
Southmead Hospital
Dorian Way
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

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 current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/01/2019		Yes	No
HRA research summary			28/06/2023	No	No