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PARAMEDIC 2: The Adrenaline Trial

Submission date
13/03/2014

Recruitment status
No longer recruiting

Registration date
19/03/2014

Overall study status
Completed

Last Edited
19/04/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A cardiac arrest occurs when the heart suddenly stops beating, and is one of the most severe medical emergencies. Over 50,000 people die each year following an out of hospital cardiac arrest (OHCA) in the UK, and less than 10% of patients survive. The immediate treatment for a cardiac arrest is cardiopulmonary resuscitation (CPR): this is a combination of rescue breathing and chest compressions. Prompt and effective CPR is essential to prevent damage to vital organs, and increases the chance of survival. If initial treatments are not effective at restarting the heart, some people are given a drug called adrenaline. Although adrenaline has been used to treat cardiac arrest for a number of years, no one is really sure about whether it is safe and effective for improving long-term survival and helping the brain to recover. Given the uncertainty of the evidence and the life-threatening nature of the condition being treated, it is ethically important that we obtain the best evidence we can to justify treatment, while ensuring that the interests of the research participants remain paramount.
When doctors, nurses and paramedics do not know whether a treatment is effective it is common to undertake a research study. Research studies of this type involve putting people into two groups where one group receive the active drug (in this case adrenaline) and the other group a dummy drug (known as a placebo). The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The study is referred to as a 'double blind trial', as neither the patient nor the paramedic/nurse/doctor will know in which treatment group someone was in. The aim of this study is to work out how safe and effective adrenaline is as a treatment for patients who suffer out of hospital cardiac arrest.

Who can participate?
Patients who suffer from a cardiac arrest in an out of hospital environment being treated with advanced life support that is initiated and/or continued by an ambulance service clinician.

What does the study involve?
The University of Warwick Clinical Trials Unit is carrying out this study with five ambulance services across the UK. We will collect information about 8,000 patients who have been treated for cardiac arrest. Half of the patients will have been treated with adrenaline and half will have been treated with placebo (dummy). The study will look at survival at 30 days after cardiac arrest

in both groups and explore the effects of adrenaline on brain function. If the patient wants to take part in the follow up this will involve completing questionnaires about their quality of life and general health at 3 and 6 months after the cardiac arrest.

What are the possible benefits and risks of participating?
For people that receive adrenaline there is the potential that a greater number will have their hearts re-started and will survive in the short term (minutes to hours). For people that receive placebo, the available evidence on long-term survival (survival to hospital discharge) suggests that some people will survive to leave hospital when they would otherwise have died if they had received adrenaline. Participants receiving placebo may also avoid the potential side effects of adrenaline (irregular heartbeat, heart attacks, adverse effects on metabolism and brain injury). Participation in the study will provide critical information about the most effective way to resuscitate future patients that sustain an out of hospital cardiac arrest.

Where is the study run from?
The University of Warwick Clinical Trials Unit is carrying out this study with five ambulance services across the UK.

When is the study starting and how long is it expected to run for?
The study started in March 2014. Data will be monitored regularly by the overseeing committees and the trial may need to stop if a difference is found early. Otherwise data will be collected for three and a half years and results will be known in 2019.

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

Who is the main contact?
Warwick Clinical Trials Unit
University of Warwick
paramedictrial@warwick.ac.uk

Study website
www.warwick.ac.uk/go/paramedic2

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-000792-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/127/126, v1.0

Study information

Scientific Title
Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest

Acronym
PARAMEDIC 2

Study objectives
Is the use of adrenaline in out of hospital cardiac arrest clinically and cost effective?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/12127126
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/115562/PRO-12-127-126.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford C REC, 21/05/2014, ref: 14/SC/0157

Study design
Pragmatic individually randomised double blind controlled trial and economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Intervention: Adrenaline 1 mg every 5 minutes
Control: Placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Survival to 30 days post cardiac arrest

Secondary outcome measures
1. Survived event (sustained ROSC, with spontaneous circulation until admission and transfer of care to medical staff at the receiving hospital)
2. Survival to hospital discharge (the point at which the patient is discharged from the hospital acute care unit regardless of neurological status, outcome or destination) 3, 6 and 12 months
3. Neurological outcome at hospital discharge, 3 and 6 months
5. Health related quality of life at 3 and 6 months
6. Hospital length of stay
7. Intensive care length of stay

Overall study start date
01/03/2014

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Cardiac arrest in out of hospital environment
2. Advanced life support initiated and/or continued by ambulance service clinician

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
8000

Total final enrolment
8014

Key exclusion criteria
1. Known or apparent pregnancy
2. Known or apparently aged under 16 years
3. Cardiac arrest secondary to anaphylaxis
4. Adrenaline given prior to arrival of ambulance service clinician

Date of first enrolment
23/12/2014

Date of final enrolment
18/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
Warwick Medical School
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Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	01/11/2016		Yes	No
Results article	results	23/08/2018		Yes	No
Results article	case study results	14/01/2020	16/01/2020	Yes	No
Other publications	analysis	01/05/2020	03/02/2020	Yes	No
Results article	results	01/07/2019	02/09/2020	Yes	No
Results article	cost-effectiveness results	27/09/2020	30/09/2020	Yes	No
Results article		01/04/2021	19/04/2021	Yes	No
HRA research summary			28/06/2023	No	No