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A randomised trial of expedited transfer to a cardiac arrest centre for non-ST elevation out of hospital cardiac arrest

Submission date
27/08/2013

Recruitment status
No longer recruiting

Registration date
14/11/2013

Overall study status
Completed

Last Edited
23/07/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Out-of-hospital cardiac arrest (OHCA) is the leading cause of death in Europe and the United States. In most cases this is due to a blockage in a coronary artery that supplies blood to the heart (myocardial infarction). This study aims to find out whether a strategy of early transfer to a specialist centre equipped at dealing with OHCA with access to facilities to treat the cause of the arrest, including unblocking of the arteries, will improve survival compared to current standard treatment.

Who can participate?
Men and women aged over 18 who have an out-of-hospital cardiac arrest

What does the study involve?
Patients are randomly allocated to receive either the intervention or the current standard of care. Patients in the intervention group are treated with an immediate transfer to hospital with specialist services to manage a patient with cardiac arrest - this hospital is able to immediately treat a heart attack if this is found to be the cause of the cardiac arrest. Patients allocated to the standard of care group receive the current best standard of care, which includes delivery to the closest emergency department.

What are the possible benefits and risks of participating?
The possible benefits include improved survival. Participating in this study will help us to determine the best urgent care for patients who have had a cardiac arrest. There is no financial benefit. If the participants survive the cardiac arrest there is a slight risk (less than 1%) of procedure-related complications. The risks of participating do not outweigh the risks of sudden cardiac death.

Where is the study run from?
The pilot study was performed in a small group of patients to see if a wider scale study is possible, was run from St Thomas' Hospital, London, UK and London Ambulance Service. The main study is performed in all the major cardiac arrest centres in London: St Thomas’ Hospital,

Barts Health, Hammersmith Hospital, Royal Free Hospital, St George's hospital, King's College Hospital, Harefield Hospital, and is being run in collaboration between King's College London, Guy's and St Thomas' NHS Foundation Trust, London School of Hygiene and Tropical Medicine and the London Ambulance Service.

When is study starting and how long is it expected to run for?
The pilot study started in November 2014 and completed recruitment in February 2016. The main study will run from January 2017 until April 2024.

Who is funding the study?
The pilot study was supported by Guy's and St. Thomas' Charitable Foundation and Zoll Medical Corporation (unrestricted educational grant).
The main study is funded by the British Heart Foundation.

Who is the main contact?
1. Prof. Simon Redwood (simon.redwood@gstt.nhs.uk)
2. Dr Tiffany Patterson (tiffany.patterson@kcl.ac.uk)

Study website
https://arrest.lshtm.ac.uk/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
125842

ClinicalTrials.gov number
NCT03872960

Secondary identifying numbers
6.0, IRAS 125842

Study information

Scientific Title
A Randomised tRial of Expedited transfer to a cardiac arrest centre for non- ST elevation out of hospital cardiac arrest (ARREST): a randomised controlled trial

Acronym
ARREST

Study objectives
Current hypothesis as of 27/09/2016:
The aim is definitively determine the best post-resuscitation care pathway for patients without ST elevation on the post resuscitation ECG. We propose that changes to emergency management comprising expedited delivery to a cardiac arrest centre (CAC) with organised post-cardiac arrest care including immediate access to reperfusion therapy will reduce mortality in patients without STE compared to the current standard of care.

Previous hypothesis:
A strategy of immediate coronary angiography after ventricular fibrillation out-of-hospital cardiac arrest confers a survival benefit compared to current standard of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East NRES Committee London, 02/01/2014, ref: 13/LO/1508

Study design
Open randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cardiac arrest

Interventions
Current interventions as of 02/05/2023:

1. The intervention arm consists of activation of a pre-hospital triaging system (currently routinely in place for post-arrest patients with evidence of ST elevation on the ECG) with pre-alert of the cardiac arrest centre and strategic delivery of the patient to the catheter laboratory (24 hours a day, 7 days a week). They will receive definitive post-resuscitation care: intubation and ventilation, where necessary, targeted temperature management and goal-directed therapies including evaluation and identification of underlying cause of arrest with access to immediate reperfusion if necessary. Prognostication will occur no earlier than 72 hours post-cardiac arrest, this protocolised prognostication will ensure premature withdrawal of life-sustaining treatment is prevented. Transfer times estimated from the 40-patient pilot are anticipated to be 100 minutes (median; IQR 75 to 113) from time of arrest to the designated centre.

2. The control arm comprises the current standard of pre-hospital advanced life support (ALS) care management for patients with ROSC following cardiac arrest of suspected cardiac aetiology. The patient is conveyed to the geographically closest emergency department. Management thereafter will be as per standard hospital protocols however as in the intervention arm, prognostication is to be delayed in trial patients until at least 72 hours post arrest.

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Previous interventions as of 27/09/2016:

1. The intervention arm consists of activation of a pre-hospital triaging system (currently routinely in place for post-arrest patients with evidence of ST elevation on the ECG) with pre-alert of the cardiac arrest centre and strategic delivery of the patient to the catheter laboratory (24 hours a day, 7 days a week). They will receive definitive post-resuscitation care: intubation and ventilation, where necessary, targeted temperature management and goal-directed therapies including evaluation and identification of underlying cause of arrest with access to immediate reperfusion if necessary. Prognostication will occur no earlier than 72 hours post-cardiac arrest, this protocolised prognostication will ensure premature withdrawal of life-sustaining treatment is prevented.
2. The control arm receives standard of care

Previous interventions:

Randomisation 1:1 into two arms through telephone randomisation:
1. Intervention arm: expedited transfer to hospital, direct to heart attack centre, immediate coronary angiography +/- percutaneous coronary intervention (PCI)
2. Control arm: standard of care
Follow up: All-cause mortality at 30 days, 6 months and 1 year (mortality tracking via central NHS database).
Study Classification (Endpoint): Safety/Efficacy

Intervention Type
Procedure/Surgery

Primary outcome measure
All-cause mortality at 30 days

Secondary outcome measures
Current secondary outcome measures as of 02/05/2023:

1. Neurological status at discharge (capped at 30 days)
2. Neurological status at 3 months
3. All-cause mortality at 3, 6 and 12 months
4. Quality of life (EQ-5D-5L) at discharge (capped at 30 days)

Previous secondary outcome measures as of 07/03/2023:

1. Neurological status at discharge (capped at 30 days)
2. Neurological status at 3 months
3. All-cause mortality at 3, 6 and 12 months
4. The composite of in-hospital major adverse cerebrovascular or cardiovascular events (MACCE): death, re-infarction, stroke, further revascularisation, bleeding and vascular complications (capped at 30 days)
5. Quality of life (EQ-5D-5L) at discharge (capped at 30 days)

Previous secondary outcome measures as of 27/09/2016:

1. Neurological status at discharge (capped at 30 days)
2. Neurological status at 3 months
3. All-cause mortality at 3, 6 and 12 months
4. The composite of in-hospital major adverse cerebrovascular or cardiovascular events (MACCE): death, re-infarction, stroke, further revascularisation, bleeding and vascular complications (capped at 30 days)
5. Quality of life (EQ-5D-5L) at 12 months

Previous secondary outcome measures:

1. All-cause mortality at 6 months and 1 year
2. Neurological status at hospital discharge, capped at 30 days
3. Major adverse cardiovascular events:
3.1. Acute myocardial infarction
3.2. Need for repeat revascularization: PCI or coronary artery bypass grafting (CABG)
3.3. Major bleeding: procedure-related complication (requiring surgery or drop in Hb >3g/dL)

Overall study start date
01/11/2014

Completion date
30/04/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 14/02/2020:
1. Out-of-hospital cardiac arrest (OHCA)
2. Return of spontaneous circulation (ROSC)
3. Aged 18 or over (known or presumed)

Previous inclusion criteria as of 27/09/2016:
1. Witnessed out-of-hospital cardiac arrest
2. Return of spontaneous circulation and 12-lead electrocardiogram
3. Age 18 or over (known or presumed)
4. No obvious non-cardiac cause (trauma, drowning, suicide, drug overdose)

Previous inclusion criteria:
1. Witnessed out-of-hospital cardiac arrest
2. Absence of non-cardiac cause (trauma, drowning, intoxication)
3. Presenting rhythm: pulseless VT or VF

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 (pilot); 860 (main trial)

Key exclusion criteria

Current participant exclusion criteria as of 14/02/2020:
1. Criteria for ST-elevation myocardial infarction on 12-Lead electrocardiogram (ECG)
2. Do Not Attempt Resuscitation (DNAR) Order
3. Cardiac arrest suffered after care pathway set and patient en route
4. Suspected pregnancy
5. Presumed non-cardiac cause (for example; trauma, drowning, suicide, drug overdose)
6. Presumed significant trauma/injury

Previous exclusion criteria as of 27/09/2016:
1. Criteria for ST-elevation myocardial infarction on 12-lead electrocardiogram
2. Do Not Attempt Resuscitation Order
3. Suspected pregnancy

Previous exclusion criteria:
1. ST-elevation myocardial infarction (STEMI) on 12-lead ECG in presence of return of spontaneous circulation (ROSC)
2. Pulseless electrical activity (PEA) or Asystole (non-shockable) as the only documented rhythm
3. Do Not Attempt Resuscitation Order (DNAR)
4. Suspected pregnancy

Date of first enrolment
01/01/2017

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
United Kingdom
SE1 7EH

Study participating centre
Barts Health
United Kingdom
E1 1RD

Study participating centre

Hammersmith Hospital
United Kingdom
W12 0HS

Study participating centre
Royal Free Hospital
United Kingdom
NW3 2QG

Study participating centre
St George’s Hospital
United Kingdom
SW17 0QT

Study participating centre
King’s College Hospital
United Kingdom
SE5 9RS

Study participating centre
Harefield Hospital
United Kingdom
UB9 6JH

Study participating centre
London Ambulance Service
United Kingdom
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Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
c/o Mrs Karen Ignatian
R&D Department

16th Floor
Guy's Tower
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

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

Results and Publications

Publication and dissemination plan
1. Results of the trial pilot: submitted for peer review
2. Trial protocol: on commencing main trial

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/10/2018		Yes	No
Other publications	pilot study	01/06/2017	17/02/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		14/10/2023	23/07/2024	Yes	No
Statistical Analysis Plan	Supplementary appendix	14/10/2023	23/07/2024	No	No