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

Submission date Recruitment status [X] Prospectively registered 27/08/2013 No longer recruiting [X] Protocol [X] Statistical analysis plan Registration date Overall study status 14/11/2013 Completed [X] Results [] Individual participant data **Last Edited** Condition category 23/07/2024 Circulatory System

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)

Contact information

Type(s)

Scientific

Contact name

Prof Simon Redwood

Contact details

Cardiovascular Division, Rayne Institute 6th Floor, East Wing St Thomas' Hospital Westminster Bridge Road London United Kingdom SE1 7EH

Type(s)

Public

Contact name

Ms Megan Knight

Contact details

Department of Medical Statistics
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 020 7927 2723
arrest@lshtm.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)

125842

ClinicalTrials.gov (NCT)

NCT03872960

Protocol serial number

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

Study type(s)

Treatment

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.

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 lifesustaining 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(s)

All-cause mortality at 30 days

Key secondary outcome(s))

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

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 United Kingdom

England

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

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust

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

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 Results article	Details		Date added 23/07/2024	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/10/2018	23/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	pilot study	01/06/2017	17/02/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	Supplementary appendix	14/10/2023	23/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes