# PARAMEDIC 2: The Adrenaline Trial

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
13/03/2014		[X] Protocol		
Registration date 19/03/2014	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 19/04/2021	Condition category Circulatory System	[] 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

## **Contact information**

Type(s)

Scientific

#### Contact name

**Prof Gavin Perkins** 

#### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2014-000792-11

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

Survival to 30 days post cardiac arrest

### Key secondary outcome(s))

- 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

#### 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

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

## Locations

#### Countries of recruitment

United Kingdom

England

CV47AL

Study participating centre
The University of Warwick
Coventry
United Kingdom

## Sponsor information

## Organisation

University of Warwick (UK)

#### **ROR**

https://ror.org/01a77tt86

# Funder(s)

## Funder type

Government

#### **Funder Name**

Health Technology Assessment Programme

#### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/08/2018		Yes	No
Results article	case study results	14/01/2020	16/01/2020	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
Protocol article	protocol	01/11/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	analysis	01/05/2020	03/02/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes