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Can a lactate measurement taken during out of hospital cardiac arrest predict the patient's survival to hospital?

Submission date
16/02/2020

Recruitment status
No longer recruiting

Registration date
18/02/2020

Overall study status
Completed

Last Edited
31/08/2022

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. NHS ambulance services attend approximately 30,000 such incidents annually to provide a treatment called resuscitation. Despite the efforts of the ambulance services, less than one in ten people survive.
When a patient's heart stops their body becomes deprived of oxygen. This lack of oxygen results in a rise of lactic acid (lactate) which, when present in sufficient levels, has been proven can predict the patient's likelihood of survival. The research to find this out was conducted in hospital but there is no evidence to suggest that lactate measured in the ambulance would produce the same results. It is possible to measure lactate accurately and rapidly in the ambulance using a small sample of blood and a small hand-held device. Results are available within seconds and may be valuable to the paramedic when making decisions regarding treatment.
This research will test if lactate readings taken during a resuscitation attempt by a paramedic can predict a patient's likelihood of surviving to hospital. The researchers will do this by looking at data already collected by the ambulance service. In addition to the lactate readings all patients will continue to receive normal treatments.

Who can participate?
Persons aged 18 years and older who are eligible for resuscitation in accordance with current Resuscitation Council guidelines.

What does the study involve?
The study involves collecting blood lactate measurements from adult patients suffering a medical out of hospital cardiac arrest. Data will be collected in the field by study trained paramedics and reported to the research team. The researchers will then correlate the lactate measurements for individual patients with specifics about each event and individual outcomes.

What are the possible benefits and risks of participating?
The benefits of participating in this study are that participants will be contributing towards our understanding of lactate in out of hospital cardiac arrest and if a lactate measurement is

prognostic of survival. Any risks should be minimal. All participants will continue to receive standard care as a result of being involved in this study and study involvement will not affect patient outcome. Data will be collected, stored, used and destroyed in accordance with the Data Protection Act and GDPR guidelines and will only be accessible by the research team.

Where is the study run from?
North East Ambulance Service NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2021 (updated 12/08/2020, previously: September 2020 (updated 06/07/2020, previously: June 2020))

Who is funding the study?
CRN North East and North Cumbria Investigator Initiated Commercially Funded Research Studies (IIT) PA allocation Award Scheme (UK)

Who is the main contact?
Karl Charlton
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Study website
https://www.neas.nhs.uk/our-services/research-and-development/predict-study.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271249

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
02072019, IRAS 271249

Study information

Scientific Title
PaRamEDIc assessment of laCTate in out of hospital cardiac arrest: measuring the association with survival to hospital

Acronym
PREDICT

Study objectives
Can a lactate measurement taken during an out of hospital cardiac arrest predict the patient's survival to hospital?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/11/2019, Yorkshire and Humber – Bradford Leeds research ethics committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8018; nrescommittee.yorkandhumber-bradfordleeds@nhs.net), ref: 19/YH/0363, Confidentiality Advisory Group (CAG: 19/CAG/0201)

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Diagnostic

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
During their cardiac arrest eligible participants will undergo a point of care blood lactate measurement. This is the only intervention participants will receive in addition to standard care. Some participants will not be transported to hospital and will be followed until the end of their episode of care. Some participants who are transported to hospital will not survive to discharge and these patients will be followed to 30 days, as will all survivors.

Study paramedics will use a Nova Biomedical Stat Strip Xpress point of care lactate device to measure blood lactate from eligible participants. The blood lactate reading will be available to the paramedic in 13 seconds and will be recorded. The researchers will collect all the lactate readings and correlate this with data surrounding the cardiac arrest and patient outcome.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nova Biomedical Stat Strip Xpress

Primary outcome measure
Survival to hospital measured by the return of spontaneous circulation (ROSC)

Secondary outcome measures
1. ROSC rate at any time
2. 30-day mortality

Overall study start date
02/07/2019

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. Eligible for resuscitation in accordance with current Resuscitation Council guidelines
3. Absence of do not attempt resuscitation (DNAR) order
4. In the catchment area of Newcastle upon Tyne Hospitals NHS Foundation Trust

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
111

Key exclusion criteria
1. Known or apparent pregnancy
2. Blunt or penetrating injury as primary cause of cardiac arrest
3. Absence of peripheral venous access

Date of first enrolment
18/02/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East Ambulance Service NHS Foundation Trust Ambulance Headquarters
Bernicia House
Goldcrest Way
Newburn Riverside
Newcastle upon Tyne
United Kingdom
NE15 8NY

Sponsor information

Organisation
North East Ambulance Service NHS Foundation Trust

Sponsor details

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Goldcrest Way
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Newcastle upon Tyne
England
United Kingdom
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+44 (0)191 430 2295
michelle.jackson@neas.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.neas.nhs.uk

ROR
https://ror.org/02mphet60

Funder(s)

Funder type
Government

Funder Name
CRN North East and North Cumbria Investigator Initiated Commercially Funded Research Studies (IIT) PA allocation Award Scheme

Results and Publications

Publication and dissemination plan
Findings will be published in relevant medical journals, at conferences and to members of the public via the patient public outlets at North East Ambulance Service.

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Study data will be stored on a secure, password protected North East Ambulance Service Trust server and access will be strictly limited to the research team at North East Ambulance Service. All electronic will be anonymised. Paper documents in the form of consent forms will be stored securely in a locked filing cabinet in the research and development department at North East Ambulance Service NHS Foundation Trust and access to this will be strictly limited to the research team. Consent forms will be linked to electronic data

by a linking document which will be stored separately and electronically on a North East Ambulance Service NHS Foundation Trust server, access to which will be strictly limited to the research team. All data will be stored in accordance with the Data Protection Act (2018) and the General Data Protection Regulation (GDPR) (2019).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		17/03/2022	17/03/2022	No	No
Protocol article		02/03/2021	31/08/2022	Yes	No
HRA research summary			26/07/2023	No	No