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The impact of introducing real-time feedback on ventilation rate and volume by ambulance clinicians in out-of-hospital cardiac arrest

Submission date
18/08/2022

Recruitment status
No longer recruiting

Registration date
18/08/2022

Overall study status
Completed

Last Edited
05/09/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiac arrest is a life-threatening emergency. It occurs when the heart suddenly stops beating. This is different to a heart attack, which is where the heart is damaged but continues to beat. When the heart stops beating it cannot pump blood to the brain, lungs and other organs. Within seconds of a cardiac arrest, a person will become unconscious and unresponsive. When a cardiac arrest occurs in the community, outside of a hospital setting, it is called an out-of-hospital cardiac arrest (OHCA). It is an emergency that requires urgent treatment if the patient is to have the best chance of survival.
When an ambulance clinician attends to a person suffering an OHCA, they are required to deliver chest compressions, which involves pushing up and down on the patient's chest, and to assist with breathing, which involves inserting a tube into the patient's mouth, and squeezing a bag inflated with oxygen to assist or take over a patient's breathing. This is called ventilation.
When delivering oxygen, it is important to deliver the right amount. There is guidance about how much oxygen to deliver with each rescue breath, and how often each breath should be delivered, although it is very difficult for ambulance clinicians to adhere to this guidance as until recently it has been impossible to know exactly how much oxygen is being delivered.
Previous research suggests ambulance clinicians frequently deliver too much oxygen and this is known to affect survival, and that paramedic compliance with guidance can be improved with real-time visual feedback.
This study aims to determine whether introducing real-time ventilation feedback improves compliance with recommended rate and volume of ventilation in clinical practice during OHCA.

Who can participate?
Patients aged 18 years and over who are eligible for resuscitation in accordance with current European Resuscitation Council guidelines in the catchment area for South Tees Hospitals, University Hospital of North Tees, Newcastle Hospitals or Northumbria Specialist Emergency Care Hospital, when the study paramedics are first on the scene

What does the study involve?
When a clinician attends a patient who is suffering from a cardiac arrest (their heart stops

beating) a new real-time visual feedback device will be used which has been developed that attaches to the tube that is inserted into the patient's mouth. The other end of the device connects to the defibrillator screen used by ambulance clinicians. When an ambulance clinician squeezes the bag to provide oxygen, the amount of oxygen given appears on the screen, so the paramedic can respond to any under- or over-delivery of oxygen. A 5-second counter tells the paramedic when to squeeze the bag at the right time.

What are the possible benefits and risks of participating?
There will be no personal benefit to participating in this study. However, there may be a wider benefit to other patients and the research community.
The overall risk of conducting this study is low. All patients will receive full standard care whilst participating in this study and all clinical decisions and interventions will remain the same regardless if the attending ambulance clinician receives ventilation feedback or not. Study clinicians will be trained in how to use the ventilation feedback device and how to interpret the visual feedback during a training session. All equipment used in the study is standard equipment that ambulance clinicians will be familiar with.

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

When is the study starting and how long is it expected to run for?
January 2021 to February 2022

Who is funding the study?
Zoll Medical UK

Who is the main contact?
Mr Karl Charlton, Karl.charlton@neas.nhs.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49221, IRAS 295868

Study information

Scientific Title
The impact of introducing real-time feedback on ventilation rate and volume by ambulance clinicians in out-of-hospital cardiac arrest: the VANZ2 study

Acronym
VANZ2

Study objectives
Observational human studies suggest rescuers frequently deliver ventilations outside of European Resuscitation Council (ERC) recommendations and that hyperventilation during resuscitation is common. Hyperventilation and/or excessive ventilations are known to be associated with suboptimal outcomes. Technology now exists to inform clinicians about the rate of ventilation and tidal volume (Vt) delivered during resuscitation. Zoll Medical Corporation have developed a non-invasive, real-time ventilation feedback device (VFD) called the Accuvent and the study hypothesised that this device would improve rescuer ventilation compliance with ERC recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2021, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 785738; Wales.REC1@wales.nhs.uk), ref: 21/WA/0145

Study design
Randomized; Both; Design type: Treatment, Process of Care, Device, Cross-sectional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet
See trial outputs table

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

Interventions
This study is a stepped wedge, cluster randomised trial (Hemming et al, 2015), involving three ambulance stations: Blucher, Redcar and Middlesbrough. This design has been chosen so patients are not directly randomised, rather the treating stations are randomised, and the intervention (the real-time feedback device is 'turned on' randomly). This is essential so the researchers can collect control data (currently absent from standard paramedic practice) and intervention data, to support the scientific aspects of the study.

It is important to note that all patients will continue to receive full standard care as a result of study participation. Some patients will receive care in addition to standard care (when the feedback device is 'turned on'), but no patients will receive anything less than standard care.

Objectives and outcomes
The main objective is to determine any change in compliance with ventilation guidelines due to real-time feedback. The main outcome is to demonstrate that 40% of clinicians involved in the study can deliver ventilations that are ≥75% compliant with European Resuscitation Council guidelines.

Hypothesis
The null hypothesis for the primary outcome of this study is that the feedback will have no effect on paramedic ventilation compliance. The alternative hypothesis (H1) is that ventilation compliance will change with the use of feedback.

Study procedure
Clinicians based at each ambulance station will form a cluster. Initially, no cluster will be exposed to real-time ventilation feedback and all will be control clusters. All control clusters will use the real-time ventilation feedback device but will receive no feedback. Each month, one cluster will be randomised to ‘switch on’ the real-time feedback and will move from control to intervention, until all clusters are exposed to real-time ventilation feedback and are using the feedback during OHCA. At the end of the study there will be a period when all clusters are exposed. Data collection continues throughout the study so that each cluster contributes observations under both control and intervention observation periods.

Each cluster will be allocated a unique cluster number: Redcar = 1, Middlesbrough =2, Blucher = 3. Prior to the commencement of the study, each cluster will be randomised to the order in which they will have the real-time ventilation ‘turned on’. This order will not be altered.

Study paramedics will screen patients for eligibility when they attend an OHCA. If the patient meets the eligibility criteria, the study paramedic will enrol the patient into the study and use the ventilation feedback device when ventilating the patient. Patients will receive full standard care in addition to the ventilation feedback device.

When a patient has been enrolled in the study and the resuscitation has been completed, the study paramedic will text the unique incident number to a secure study mobile telephone held

by the research paramedic, to inform them of enrolment. All recruited patients will be allocated a unique study identification number by the research paramedic, who will access the patient's ePCR to determine if they have been conveyed to the emergency department (ED). Patients who have been conveyed to ED will be tracked remotely by the research team.

The research paramedics will screen North East Ambulance Service OHCA audit reports for missed recruitment opportunities and check for patient enrolment that has not been reported to the research team.

Follow up
Patients conveyed to hospital will be followed remotely by the research team. Patients who have died during the index visit will have their study data collected, entered onto the study database then anonymised. Patients who have survived will be visited at the earliest opportunity during the index visit by a research paramedic. Patients who have been declared deceased on scene and have not been conveyed will remain in the study and the research paramedic will collect their study data from the ePCR and enter it into the study database. This data will be anonymised immediately.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
Compliance with ERC guidelines for ventilation, comprising tidal volume (Vt) delivered with each rescue breath and ventilation rate per minute. ERC guidelines recommend ventilating patients with 8-12 ventilations per minute and a tidal volume (Vt) of 500-600 ml. These data are collected during the out-of-hospital resuscitation period.

Secondary outcome measures
1. Effect on other aspects of care during resuscitation (such as compliance with chest compression guidelines (ERC guidelines regarding rate and depth), evidence of delay in time to defibrillation, time to receive first drug etc). These data are collected during the out-of-hospital resuscitation period.
2. Patient outcomes:
2.1. Return of spontaneous circulation (ROSC) at any time
2.2. Survival to the emergency department (ED)
2.3. Short-term survival (survival to 24 hours)
2.4. Long-term survival (survival to 30 days)
2.5. Neurological function measured using mRS (modified Rankin scale) at 30 days

Overall study start date
12/01/2021

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. All persons aged 18 years and over
2. Eligible for resuscitation in accordance with current European Resuscitation Council guidelines
3. Absence of do not attempt resuscitation (DNAR) order
4. Catchment area for South Tees Hospitals, University Hospital of North Tees, Newcastle Hospitals or Northumbria Specialist Emergency Care Hospital
5. Study paramedics first on scene

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Key exclusion criteria
1. Known or apparent pregnancy
2. Traumatic OHCA

Date of first enrolment
01/08/2021

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East Ambulance Service NHS Foundation Trust
Bernicia House
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Sponsor information

Organisation
North East Ambulance Service NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/02mphet60

Funder(s)

Funder type
Industry

Funder Name
ZOLL Medical Corporation

Alternative Name(s)
ZOLL, Zoll Medical Corp., ZOLL Medical, ZMC

Funding Body Type
Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The researchers intend to present study findings at research conferences as both oral and poster presentations. The study manuscript is currently under peer review with the British Paramedic Journal.

Intention to publish date
28/02/2023

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 non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	26/05/2021	18/08/2022	No	Yes
HRA research summary			28/06/2023	No	No