The Ventilation Accuracy in NEAS using Zoll feedback (VANZ2) study

PARTICIPANT INFORMATION SHEET

You have been given this leaflet to read and consider because you were taken to hospital after suffering a cardiac arrest (your heart stopped beating) and the North East Ambulance Service that treated you is involved in a clinical trial, called the VANZ2 study.

Information about this research

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 a person suffering an OHCA, they are required to deliver chest compressions, which involves pushing up and down on the patients' chest, and to assist breathing, which involves inserting a tube into the patients' mouth, and squeezing a bag inflated with oxygen to assist or take over a patients' 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 effect survival, and that paramedic compliance with guidance can be improved with real time visual feedback.

A new real time visual feedback device has been developed that attaches to the tube that is inserted into the patients' 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 five second counter tells the paramedic when to squeeze the bag at the right time.

What is the purpose of this research?

The purpose of this research is to explore the use of the visual feedback device in clinical practice during cardiac arrest, and to gain an indication if this improves patient survival. We will also measure the quality of other aspects of each resuscitation to ensure the use of visual feedback does not have an adverse effect.

Who has funded this research?

This research is supported by Zoll Medical UK, who make the visual feedback device, and who have provided the equipment needed to conduct this research. Additional support has been provided by the Academic Health Sciences Network (North East & North Cumbria).

Why have I been chosen?

During your resuscitation you received oxygen by the ambulance clinicians who used the feedback device to help with their ventilations. **This means you have already been included in this research.** When your heart stopped you lost consciousness immediately. As a result, the ambulance clinicians were unable to discuss with you your views about participation in this study at the time of your cardiac arrest. It was also not possible for the ambulance clinicians to speak to those close to you to obtain consent as this may have delayed your emergency treatment. We are now asking your permission to continue participating in this research.

What will happen if I want to take part?

If you want to continue to participate, the researcher who has visited you will ask you to complete a consent form. The consent form will need to be signed and dated. One copy will be retained by the researcher and one copy by you. The research team will then collect information about you and your treatment. We can do this by looking at data already collected by the ambulance service and we will not need to contact you again.

Do I have to take part?

You do not have to take part and it is your right not to participate in this study. If you decide not to take part in this study it will not affect the care you receive in any way. You are free to stop participating in this study at any time. If you choose to stop participating in this study please contact the research team and we will destroy all of your study data.

What are the benefits and risks to participating?

There will be no personal benefit to participating in this study. However, there may be wider benefit to other patients and the research community. The risks to participating in this study are small.

Will my data be secure?

All data collected from you will be kept strictly confidential and will only be seen by the research team working on this study, who are bound to a duty of confidentiality to you, as a research participant. Your data will be stored in accordance with the Data Protection Act (2018) and your anonymity will be guaranteed.

How will we use information about you?

We will need to use information about you and from your medical records for this research project. This information will include your initials, NHS number, name and contact details as well as information about the care you received by North East Ambulance Service NHS Foundation Trust and the hospital you were taken to. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Where can you find out more about the study or how your information is used?

You can find out more about the study by asking one of the research team or by contacting the Chief Investigators, Karl Charlton and Dr Graham McClelland at either karl.charlton@neas.nhs.uk or graham.mcclelland@neas.nhs.uk. Alternatively, please telephone 0191 430 2294 or write to North East Ambulance Service NHS Foundation Trust, Ambulance Headquarters, Bernicia House, Goldcrest Way, Newburn Riverside, Newcastle upon Tyne, NE15 8NY. You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients.

Who do I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. If you wish to make a complaint you can contact the research team on the contact details above, or please address your complaint to Freepost PALS, or Freephone 0800 0320202 or email northoftynepals@nhct.nhs.uk

Thank you for taking the time to read this participant information sheet.