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PROTECT Airways Study

Participant Information Leaflet

A research study to find out if an alternative airway system is better than standard care for patients connected to a breathing machine

Chief Investigator: Dr Gareth Kitchen
Co-chief Investigator: Prof Paul Dark

- This information sheet explains the Protect Airways study and what taking part will involve.
- This study is looking at an alternative airway system, a type of tube that connects critically ill patients to a breathing machine (ventilator), compared to the tube normally used as standard care. The study is looking to find out if the alternative airway system shortens the duration of intensive care unit care and is good value for money.
- You are being approached as you are currently in hospital and your doctor has decided that you need a ventilator.
- The alternative airway system being tested is already approved for use in the NHS and is available in some hospitals, so we do not anticipate any serious risk to you by taking part.
- If you decide that you would like to take part, we will ask you to read this information and sign a consent form.
- We will collect identifiable data from your medical records and national datasets and ask you to complete questionnaires at 2 and 6 months after entering the study to see how you are getting on.
- We will keep you fully informed during the study so you can let us know if you have any concerns.

- If you are unsure about taking part in the study, you may seek independent advice. We will understand if you do not want to take part.
- If you do not wish to take part in this study, it will not affect your standard of care in any way.
- The University of Warwick is currently leading several studies looking at how we treat patients in this setting. You may already be in one of those studies. If so, we may share information between these studies to reduce what we need to ask from you.

Before you decide, please read the information carefully to understand why the research is being done. Talk to others about the study if you wish and please feel free to ask us any questions.

There is a second information leaflet which describes how we will use data collected about you.

Why are we doing this study?

A breathing tube is the pathway through which air flows into the lungs. Intensive care units (ICU) are specialist hospital wards that provide treatment and monitoring for people who are very ill. Close to 184,000 patients annually are admitted to NHS ICUs and 33% require help with their breathing, using a machine which is called invasive mechanical ventilation. Treatment involves placing a plastic tube through the mouth into the windpipe and attaching the person to a breathing machine (ventilator). A serious complication of this life-saving treatment is a chest infection or ventilator associated pneumonia (VAP) which affects 20% of people on ventilators. It occurs when mucus, a jelly-like liquid that lines your lungs, throat, mouth, nose, that is infected drips down the back of the throat past the plastic tube into the lungs. Whilst VAP can be treated with antibiotics, some people will die and others will spend much longer on a ventilator.

The alternative airway system aims to improve the windpipe seal and reduce the risk of infected mucus passing down into the lung, by maintaining the inflation of the protective cuff. Patient studies suggest this system is safe and effective at removing mucus and preventing lung infection. Some hospitals are using the alternative airway system. However, we do not know if the positive findings seen in a few hospitals would also be seen in the wider NHS, and whether the new tube is good value for money, resulting in benefit to patients. The National Institute for Health and Care Excellence (NICE), the organisation that provides guidance for health and care practitioners to deliver the best care, has therefore recommended a large-scale research study to see if this equipment is needed.

Why am I being approached to take part in this study?

You are currently in hospital and your doctor has decided that you need a ventilator.

Who is eligible for the study?

Patients who are:

- Adult (age ≥18 years).
- Needing invasive mechanical ventilation.
- Likely to remain on a ventilator for at least 24 hours following study entry.

In total we will be including 2194 patients from across the UK in this study

Do I have to take part?

No, taking part in this study is completely voluntary. Even if you agree to be in the study, you can change your mind and withdraw at any time without giving a reason just by telling the healthcare team looking after you. We will keep the data we have already collected, and we will ask permission to continue to collect some data. This is important to make sure the study results are valid. You will receive the same standard of care, and this decision will have no influence on further treatment.

What does this study involve?

If after reading the information leaflet you would like to take part, we will ask you to sign a consent form. We will give you a copy of this information leaflet and the form to keep.

You will then be assigned by chance (known as randomisation) to one of two groups:

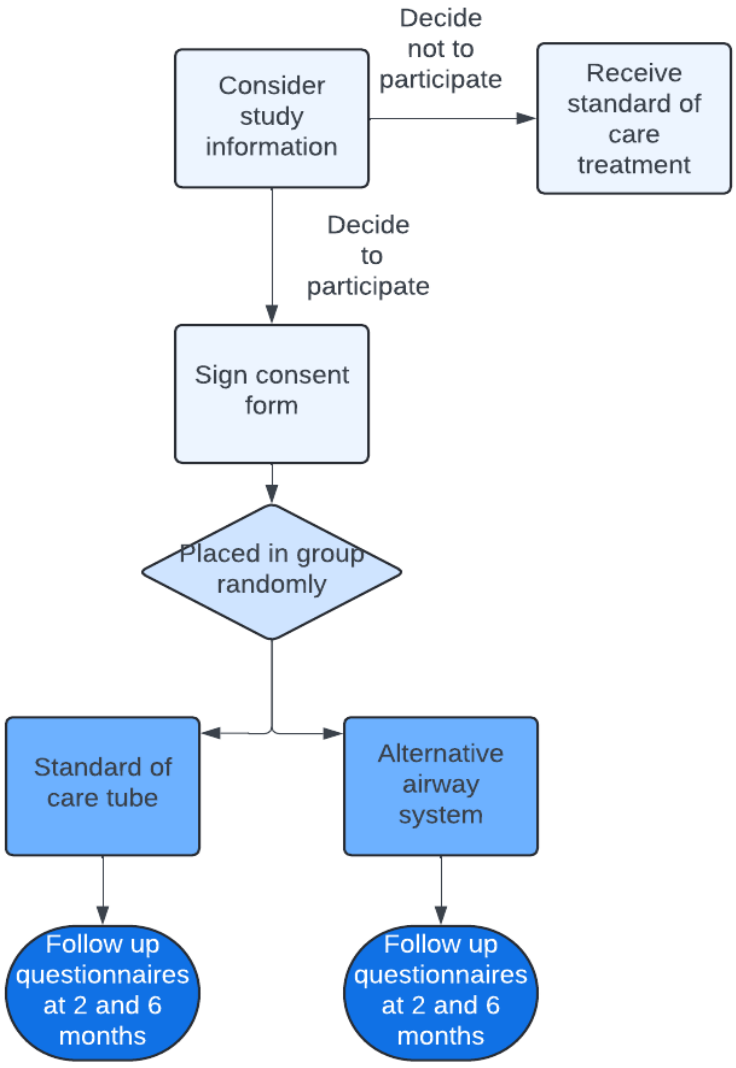
1. Alternative airway system: This is similar to the standard care tube, and in addition has a system to ensure the seal to the patient is maintained and has multiple ports to remove secretions (fluids).
2. Standard care: The tube usually used by your hospital will be used.

There will be no other changes to care given to patients in both alternative airway system and standard care group.

You, or the hospital team will not be able to choose which group you are in. This is decided by a computer at random (known as randomisation). This process ensures there is an equal chance of being placed in either group and is the best way to ensure that there is a fair comparison between both tubes.

The research team will collect information about care you receive while in hospital including how the ventilator is used, how long you need the ventilator, and how long you stay in hospital. The research team will collect your personal information such as age, ethnicity, sex and past medical conditions before coming to critical care as this helps us to understand the effect of the tube on different groups of people.

You will be sent a questionnaire two and six months after entering the study asking about your overall wellbeing and any healthcare you have used. Each questionnaire will take approximately five to ten minutes to complete. If needed, someone can complete them on your behalf. We will share your name, email address, and phone number with a third-party company in order to send the questionnaires by text message or email. We may also get in touch with you by phone, text message or email if we have any queries about your questionnaire or if we have any updates related to the study.



How long does the study last?

You will remain in the study for six months after entering the study to complete the questionnaire about your overall wellbeing and any healthcare you have used.

What are the benefits of taking part?

As this is a research study, you may or may not experience a direct benefit. However, the findings of the study may help people needing a ventilator in critical care in the future.

There is no payment for taking part in this study. However, to thank you for your time in completing the follow-up questionnaires at two-months and six-months we will provide a gift voucher.

The University of Warwick is currently leading several studies looking at how we treat patients with respiratory (lung) failure. This group of studies is called the 'Confederation of Respiratory Critical Care Trials' or 'CoReCCT'. If you are taking part in other studies within the CoReCCT family, you will not need to complete questionnaires for each study. You will only be asked to complete the questionnaires once and will receive one voucher with each questionnaire.

What are the risks of taking part?

The alternative airway system is approved for use in the NHS and already used as part of standard care in some hospitals. Therefore, we do not anticipate any serious risk to you specific to being in the alternative airway system group. However, all patients who are very sick and need a ventilator are at risk of complications such as damage to the lungs or needing the tube to be put back in after it is removed due to ongoing problems with breathing. Some very sick patients may even die.

What if new information becomes available?

Sometimes during a research study, new information becomes available about the study treatment(s). If this information changes your involvement in the study, the study treatment may be stopped and you will continue to receive the standard care.

Will my taking part in this study be kept confidential?

The University of Warwick is the study sponsor and data controller and will be using information from your medical records to undertake this study. This means that they are responsible for looking after your information and using it properly. Please read the CoReCCT "Data Information Leaflet" document to find out more information about how we will use and keep your personal data safe.

Who is organising and paying for the study?

This study is sponsored by University of Warwick and is being coordinated by the Warwick Clinical Trials Unit. The study is funded by

the National Institute for Health Research, Health Technology Assessment (NIHR156500).

Who has reviewed this study?

People with personal experience of having respiratory (lung) failure and other members of the public have helped design and set up this study.

Research in the NHS that involves patients is reviewed by an independent group of people called a Research Ethics Committee (REC). This committee is there to protect your interests. This study has been reviewed and been approved by the XXXXXX REC.

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What happens if something goes wrong?

It is very unlikely that anything will go wrong as a result of taking part in this research. If you feel that you have been harmed during your treatment there are no special compensation arrangements. The University of Warwick will provide indemnity for this study. If you are harmed due to someone's negligence, depending upon the problem, you may have grounds for legal action but you may have to pay for it.

Depending upon the problem NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team, this liability cover may apply.

Non-negligent harm by NHS staff is not covered by the NHS indemnity scheme. The University of Warwick, therefore, cannot agree in advance to pay compensation in these circumstances

If you have any concern about any element of this trial, you can contact the researchers at your hospital: **[insert PI contact details]**

You can also seek independent advice from your local Patient Advice and Liaison Service (PALS). They can be contacted at: **[insert local PALS details]**

The study is covered by the NHS and University of Warwick's insurance and indemnity cover. 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 remain unhappy, please send your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Head of Research Governance, Research & Impact Services
University House, University of Warwick

Coventry, CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

Thank you for taking the time to read this information and for considering your participation in this study.

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