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PROTECT Airways Study
Follow Up 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

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Co-chief Investigator: Prof Paul Dark

- We are inviting you to carry on taking part in a study called PROTECT Airways.
- You do not have to continue to take part if you do not want to. If you decide to continue to take part, you can change your mind at any time by telling the healthcare professionals looking after you. This will not affect any other care that you receive.
- You have recently been unwell and were placed on a breathing machine (ventilator). At the time, the healthcare professionals looking after you felt that you were too unwell to make decisions about taking part in the study, so if there was time the study was discussed with your relative/friend or an independent healthcare professional. The decision was made to put you in the study. As you are now getting better, it is now possible to discuss the study with you.
- This study is looking at an alternative airway system, a type of tube that connects critically ill patients to the 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 were either given the alternative airway system or tube used in standard care. The group that you were placed in was decided randomly.

- You are now in the follow-up stage of the study, and we would like to continue to collect information about you to see how well you recover.
- In this study we will use information from your medical records and some national healthcare databases and ask you to complete questionnaires at 2 and 6 months after entering the study to see how you are getting on.

Please read this information leaflet which provides an overview of the study, to help you decide if you wish to continue to take part. One of the hospital research team will go through this with you and answer any questions you have. Please talk to others about the study if you wish and please feel free to ask any questions.

An online and video version of the information leaflet is available on the study website www.warwick.ac.uk/protectairways/public or accessed by scanning the QR code below

There is separate data information which describes how we will use data collected about you and can be accessed on the study website, via the QR code or a member of staff can print a copy for 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 a breathing machine, known as invasive mechanical ventilation. Treatment involves placing a plastic tube through the mouth into the windpipe and attaching the person to a breathing machine known as a ventilator. A serious complication of this life-saving treatment is a chest infection or

ventilator associated pneumonia (VAP) and affects 20% of people on ventilators. It occurs when mucus, a jelly-like liquid that 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 breathing machine.

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 these systems are 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.

How was I eligible for this study?

You met the following criteria:

- Adult (aged18 years and older).
- Needed invasive mechanical ventilation.
- Likely to remain ventilated 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 continue to take part in this study

No, continuing to take part in this study is completely voluntary. Even if you agree to continue you can change your mind and withdraw at any time just by telling the healthcare team looking after you without giving a reason. We will ask permission to keep the data we've already collected about you and 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 any further treatment.

What does this study involve?

You were previously placed into one of two groups by chance:

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 was used.

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

You, or the hospital team did not get to choose which group you were in. This was decided by a computer at random (known as randomisation). This 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.

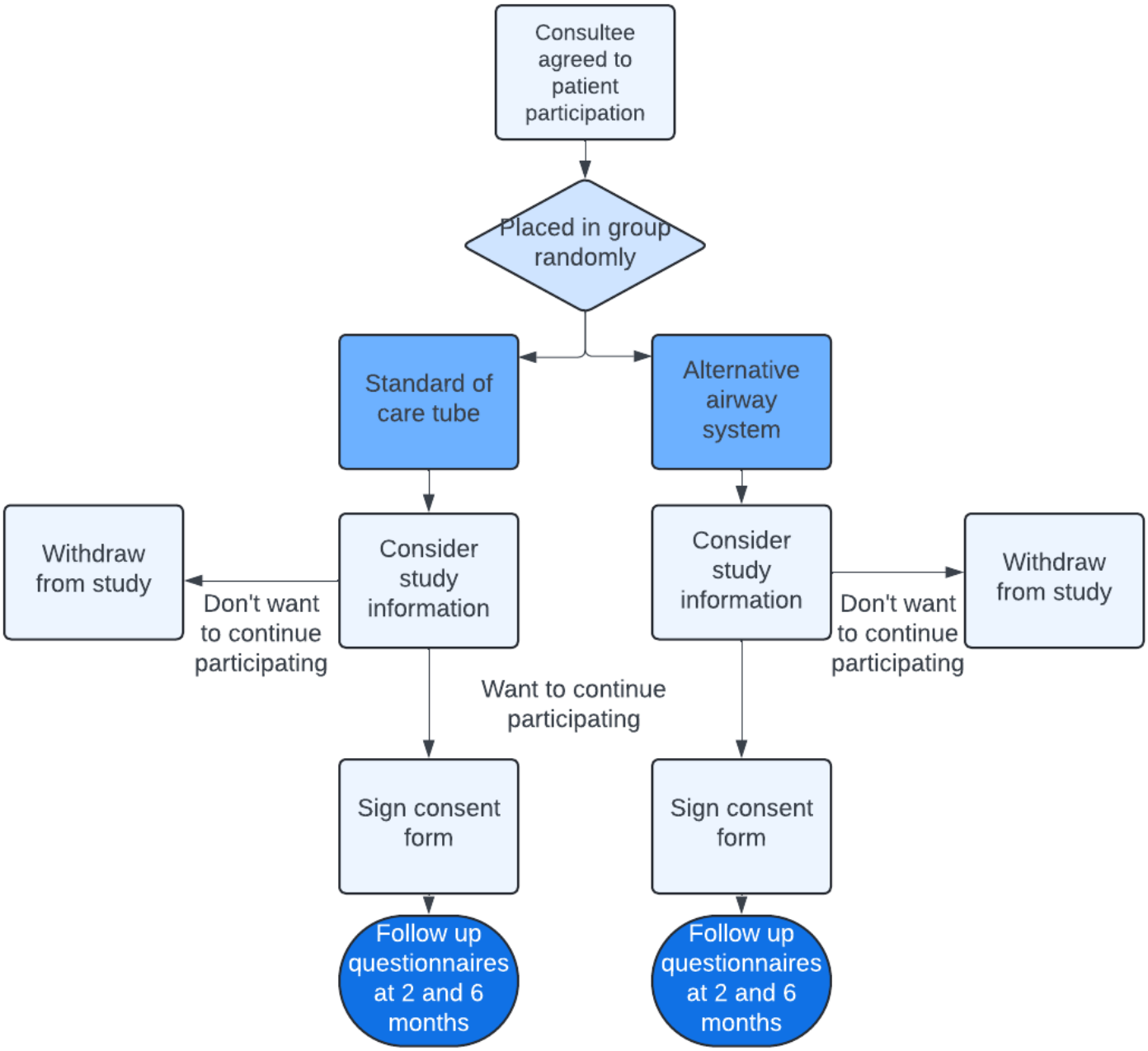
You are now in the follow up stage of the study and we would like to continue to collect information about you to see how well you recover. If you are happy to carry on taking part, we will ask you to sign a consent form. We will give you a copy of your signed consent form and this information leaflet to keep.

The research team has and may continue to collect information about the care you receive while in hospital including how the ventilator was used, how long you needed 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 at 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 send you the questionnaires via post or collect your answers to the questionnaire via telephone. We may also get in touch with you by phone, text message or email if we have any queries about your questionnaires or if we have any updates related to the study.

Please take whatever time you need to decide whether or not to continue to take part. You may wish to talk to family members and/or friends.

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'. We may have approached your family, friend or independent healthcare professional about other research studies within the CoReCCT family of studies that you may have been able to take part in.



How long does the study last?

You will remain in the study for six months after entering the study to complete the questionnaires 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 research study. However, to thank you for your time in completing the follow up questionnaire at 2 months and 6 months, we will give you a gift voucher alongside each questionnaire. 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 ICUs. Therefore, we did not anticipate any serious risk to you compared to the usual risks associated with a stay on critical care.

At this time, there are no important disadvantages or risks to taking part.

Will my taking part in this study be kept confidential?

The University of Warwick is the study sponsor and data controller. They will use information about you to undertake this study. In this research study we will use information from you, your medical records, your GP and healthcare databases such as NHS England. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

For more details on how your data will be used and kept safe, please take a look at the data information by visiting www.warwick.ac.uk/protectairways/public or scanning the QR code at the end of this leaflet. Alternatively please ask a member of staff to print a copy for you.

Who is organising and paying for the study?

This study is being sponsored and carried out by the University of Warwick, in partnership with NHS hospitals across the United Kingdom. The study is being coordinated by Warwick Clinical Trials Unit. The study is funded by the National Institute for Health and Care 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 Wales REC2 and Scotland A REC.

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 study 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 study, you can contact the researchers at your hospital: **[insert PI contact details]**

You can also seek independent advice via **[insert local PALS details or equivalent]**

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

Contact for further information:

If you have any questions about the study, either now or in the future, you may contact your local hospital research team at <<local research contact details>>

You may also wish to seek the advice of an independent contact who has knowledge of the study but is not directly involved with the study <<independent contact details>>

Alternatively, please contact
Warwick Clinical Trials Unit.
Email: protectairways@warwick.ac.uk

An online and video version of the information leaflet is available on the study website www.warwick.ac.uk/protectairways/public or accessed by scanning the QR code below

Thank you for taking the time to read this information and for considering to continue taking part in this study.

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