

<Insert Trust Logo>



## **PROTECT Airways Study**

### **Easy Read Consultee 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

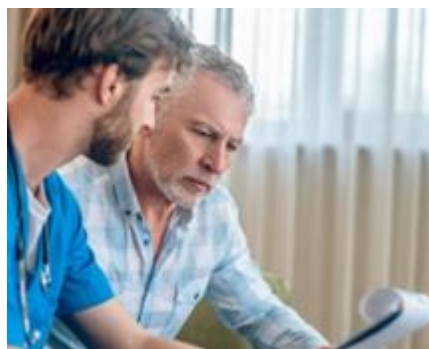
You have been given this information leaflet because your relative/friend is unable to decide for themselves whether to participate in this research. To help



decide if they should join the study, we would like to ask your opinion whether or not they would want to be involved.



Your relative/friend does not have to take part if you do not want them to.



This information sheet gives you some information about the study. There are some additional sheets that explain things in more detail. Please ask if you have any questions.



We are approaching you as your relative/friend's doctor has decided they need a breathing machine, known as invasive mechanical ventilation, as they cannot breathe on their own.



Invasive mechanical ventilation involves placing a tube into the windpipe which connects to a breathing machine know as a ventilator. This system 'takes over' breathing for the patient. This process has some unwanted effects like an infection called Ventilator Associated Pneumonia (VAP)


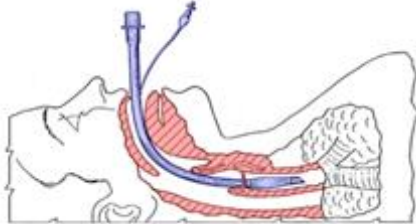
## What are we doing?



We are conducting a study across UK hospitals to compare using an alternative airway system to connect the patient 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.

## What happens in the research study?

In the study, patients are put into one of two groups to

<p data-bbox="256 193 474 361">1</p> <p data-bbox="496 193 711 361">2</p> 	<p data-bbox="824 205 1416 684">decide if they will receive the alternative airway system (shown in the picture) or the tube used as standard care. This is decided by chance by a computer. You and your relative/friend's doctors will not get to choose.</p>
	<p data-bbox="824 810 1393 1163">Everyone in the study will receive all other treatments that they need. The only difference is the type of tube used for mechanical ventilation.</p>

## Deciding to be in the study



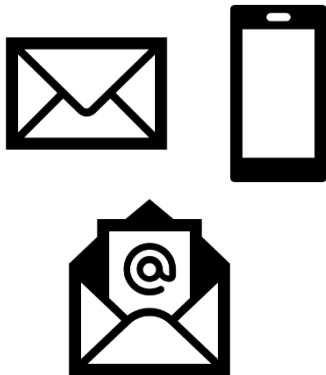
Please ask the staff if you have any questions about the study.

If you decide that your relative/friend would wish to be in the study, you will be asked to sign a declaration form. You will be given a copy of the form and this information leaflet. If you decide they would not want to, your relative/friend will still receive the best care that the hospital can give.

## Collecting information about your relative/friend



The research team will write down what happens and how well it works. This is so we can find out which tube works best.

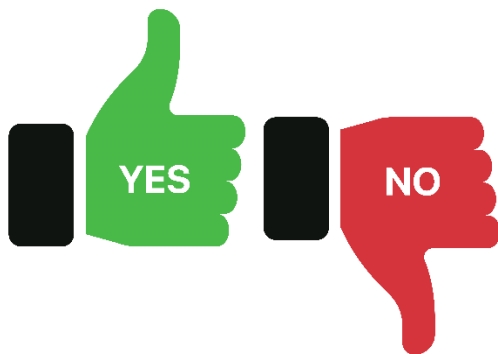


During the study, personal information about your relative/friend will be recorded. This includes their name, address, email, phone number, date of birth, ethnicity, sex and information from their medical records.



To see how your relative/friend is recovering, they will be sent questionnaires about their health at 2 months and 6 months following study entry. These will take 5 to 10 minutes to complete. To thank your relative/friend for their time, we will send them a gift voucher with each questionnaire.

## What if I change my mind?



You can change your mind at any time. You don't have to say why - just tell the healthcare team looking after your relative/friend.

We would still like to retain the information we have already collected for your relative/friend and ask

permission to collect further data if that's OK.

## How we look after your relative/friend's information



The University of Warwick is collecting all the information from the study. We will keep it safe and private.

When the study has finished, the university and the hospital that treated your relative/friend will keep the information for 5 years then delete anything that links the information to your relative/friend.

Only staff who are working on this study and who need to see your relative/friend's

	information will be able to access your relative/friend's personal information.
--	---------------------------------------------------------------------------------

## More information

This study has been reviewed and approved by Wales Research Ethics Committee 2.

You can find out more information by:

- Having a look at the more detailed information sheets, which tell you about the study and how your relative/friend's data will be used.
- Talk to the hospital staff. You can contact the hospital research team using {ADD 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>>

For information about how we (the University of Warwick) use/process information, please see:

- [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/) and [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)

- Our leaflet available from <https://warwick.ac.uk/services/legalandcompliance/services/dataprotection/privacynotices/research/>

You can contact the PROTECT Airways study team at the University of Warwick by emailing [protectairways@warwick.ac.uk](mailto:protectairways@warwick.ac.uk)

An online version of the information is available on the study website [www.warwick.ac.uk/protectairways/public](http://www.warwick.ac.uk/protectairways/public) or accessed by scanning the QR code below



Funded by  
**NIHR** | National Institute for  
Health and Care Research

This project is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (Grant Reference Numbers NIHR156500). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.