Participant Information Leaflet

The Awake Prone Study:
A research study to find out if awake prone positioning is better than standard care for patients with respiratory failure

- We are inviting you to take part in a research study called Awake Prone.
- You do not have to take part if you do not want to. If you decide to take part, you can change your mind at any time by telling the healthcare professionals looking after you.
- We are inviting people to take part who are in hospital and who are currently receiving a moderate or high amount of oxygen. The study is aiming to find out if lying on your front (awake prone positioning) or standard care (sitting up in bed) reduces the chance that someone will go on a ventilator. If you take part, which of these two groups you are in will be decided by chance.
- Individuals in the awake prone positioning group will lie on their tummy for at least 8 hours a day for up to five days.
- Doctors and other healthcare professional know that lying on your tummy is helpful if you have COVID-19, but do not currently know if awake prone positioning is helpful when you need oxygen for other conditions.
- In this study we will use information from you, your GP, your medical records and some national healthcare databases. We will only use information that we need for the 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 appropriate privacy rules. At the end of the study, we will save some of the data for future research or in case we need to check it. We will make sure no one can work out who you are from any reports we write.

Please read this information leaflet which provides an overview of the study, to help you decide if you wish 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.

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

Why am I being asked to take part in this research study?

You are currently in hospital with a condition called respiratory failure. This means you need extra oxygen to keep the oxygen levels in your blood at a safe level. There are several reasons why people have this condition. One of the most common reasons is a chest infection.

Your doctors will have started treatment for whatever condition is causing your respiratory failure. Despite this treatment, we know that some patients with respiratory failure will unfortunately get worse and may need to go on a ventilator (breathing machine) in an intensive care unit. Going on a ventilator can be lifesaving but comes with important risks. Doctors and nurses try and avoid patients going on ventilators whenever it is safe to do so.

Picture of patient lying on their tummy in a hospital bed

Normally, when patients are in hospital and need oxygen for respiratory failure, they sit upright in bed. During the COVID-19 pandemic, we found that when patients with COVID-19 laid on their tummy (awake prone positioning), it reduced the chance of them needing to go on a ventilator.

Doctors and other healthcare professionals do not currently know whether awake prone positioning helps in patients with respiratory failure not due to COVID-19.

To find out if awake prone positioning is better, patients like you are being invited to take part in this study. Some patients will lie on their tummy for at least 8 hours a day and some patients will continue to receive standard care. We will then compare how well each group recovers to see which treatment works best.

Do I have to take part?

No.

It is entirely up to you to decide. If you do not want to take part that's OK. Your decision will not

affect the quality of care you receive. If you decide NOT to take part, you and your healthcare professional will agree on which treatment you will receive. This may be the same as the treatment you would have received by taking part in this study.

What will I need to do if I take part?

If you agree to take part, we will ask you to provide consent and you will be assigned by chance to one of two groups: awake prone positioning or standard care. You, the research team, or the medical care team will not be able to choose which group you are in. This will be decided by a computer at random, just like tossing a coin or drawing lots. This type of study is called a randomised controlled study and provides the best way for researchers and healthcare professionals to know if a treatment works.

Standard care group

If you are in the standard care group, you will continue to receive standard NHS care. This means that you will normally sit upright in bed. You will receive all other appropriate treatments for your respiratory failure, such as antibiotics or other ways of giving you oxygen.

Awake-prone positioning group

If you are in the awake prone positioning group, the healthcare professionals looking after you will help you to move so that you are lying on your tummy. We ask that you lie on your tummy for at least 8 hours each day for a maximum of five days. You may be able to stop sooner if you recover more quickly. You may choose to lie on your tummy for a continuous period of 8 hours or to split this up into smaller periods of time. If you find lying on your tummy uncomfortable, the healthcare professionals looking after you will help you find ways to make it more comfortable. For the rest of the time, you may choose your position. You will receive all other appropriate treatments for your respiratory failure, such as antibiotics or other ways of giving you oxygen.

Both groups

We will collect information about everyone in both groups to see how well and how quickly they recover. We will also record whether you need to go on a ventilator; if this happens, the study will no longer ask you to lie on your front, but we will continue to collect information about your recovery. The information that we collect will include your age, sex, ethnicity and your medical information. We describe how we will use your data in our second information leaflet.

After leaving hospital, we will also ask you to complete a questionnaire about your recovery at 2 and 6 month timepoints. They will each take you 5-10 minutes to complete. If needed, someone can complete them on your behalf. We may send you the questionnaires via text, email or post, or collect your answers to the questionnaire via telephone. We may share your name, email address, and phone number with a third-party company in order to send you the questionnaires by text message or email. We will also get in touch by text message, email or telephone if we have any queries about your questionnaire or if we have any updates related to the study.

Please take what time you need to decide whether or not to take part. You may wish to talk to family members. However, if awake prone positioning does work, it is likely to work best if it is started as soon as possible.

If you are happy to take 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 University of Warwick is currently leading several studies looking at how we treat patients with respiratory failure. This group of studies is called the 'Confederation of Respiratory Critical Care Trials' or 'CoReCCT'. If you do need to go on a ventilator, we may approach you or your family about other research studies within the CoReCCT family of studies that you might be able to take part in. You do not have to take part in any of these other studies.

What are the benefits of taking part?

As this is a research study, you may or may not benefit from taking part. However, the findings of the research will help us to continually improve the treatments and care provided to patients with a similar condition now and 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 small monetary 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 disadvantages or risks of taking part?

We know that some people will find lying on their tummies uncomfortable. If you are in the awake prone positioning group, the healthcare professionals looking after you will support you to find a position on your front that is comfortable for you. Please do try and keep going with lying on your tummy as much as possible. Sometimes lying on your front can cause pressure on your skin. The healthcare professionals looking after you will encourage you to move occasionally to stop this happening. They will also help you move position to help ensure that any intravenous drips or other attachments are not dislodged when you are moving. There are no other important disadvantages or risks.

What happens if something goes wrong?

The University of Warwick will provide indemnity for this study. It is very unlikely that anything will go wrong as a result of taking part in this study however, if you are harmed due to someone's negligence, you may have grounds for legal action which you may have to pay for. NHS bodies may also be liable if you are harmed as a result of negligence whilst taking part in a clinical trial. Non-negligent harm by NHS staff is not covered by the NHS indemnity scheme, and therefore compensation may not be paid in these circumstances

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

If you have any concern about any part of this study, you can contact the researchers at your hospital: <insert PI contact details>.

You can also seek independent advice from <insert local Patient Advice and Liaison Service and contact number or relevant local contact> or follow the NHS complaints procedure in your country.

If you remain unhappy and wish to complain formally, you can do this by contacting the person below, who is a senior University of Warwick official and is independent of this study:

Head of Research Governance, Research & Impact Services
University House, University of Warwick
Coventry, CV4 8UW
Email: researchgovernance@warwick.ac.uk
Telephone: 02476 575733

What if I change my mind?

You can change your mind about taking part at any time just by telling the healthcare team looking after you. If you are in the awake prone positioning group, even if you decide that you no longer wish to lie on your tummy, we would still like to continue to collect information about you and for you to complete the follow up questionnaires. This is important to make sure the study results are valid.

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. This means that they are responsible for looking after your information and using it properly. Please read the data information leaflet, which explains how we will use and keep data safe and what you can do if something goes wrong.

Who is organising and funding the research?

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 Research, Health Technology Assessment (NIHR154796).

Who has reviewed this study?

People with personal experience of having respiratory 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 approved by Wales REC 2.

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>

Alternatively, please contact the Awake Prone study manager at the University of Warwick:
Email: awakeprone@warwick.ac.uk

An online version of this information sheet can be found on the study website www.warwick.ac.uk/awakeprone, or by scanning the QR code below:

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

The study is funded by the NIHR Health Technology Assessment (NIHR154796). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health and Care Research