UK NAVA Personal Consultee Information Sheet [Following Waiver]

Neurally Adjusted Ventilatory Assist (NAVA) in the adult critical care unit: The UK NAVA Trial

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Why are we giving you this leaflet?

- You are being given this leaflet because a family member or close friend needed to be put on a breathing machine (called a **ventilator**) in intensive care.
- We want to ask your opinion about a trial your relative/friend is in which tests a system on the breathing machine called **NAVA**.
- We could not talk to you earlier than this, because breathing machine treatments, including NAVA, were done as an **emergency procedure**.
- Your relative/friend is still too unwell for us to speak directly to them; although of course we will at the earliest appropriate time.

What is NAVA?

NAVA (stands for 'Neurally Adjusted Ventilatory Assist') and allows doctors and nurses to **see if a patient is ready to breathe on their own** and **might be able to better match the ventilator with the patient's own breaths.**

NAVA is an approved treatment. There are many studies over the last 20 years that show that adding NAVA to a breathing machine is potentially a good thing to do.

NAVA is NOT 'experimental'- it is a **fully approved** device with many potential advantages. It is not yet used much in intensive care units (ICUs) because it is a newer technology and only available on some ventilators.

NAVA uses some (invisible) electronics on a **NAVA feeding tube** to detect the patient's own breathing. **Feeding tubes** are needed in most patients in the ICU. They are usually passed through the nose and the tip sits in the stomach. **This means NAVA should not need any different procedures compared to usual care.**

Why do we need to do a trial?

Although in theory NAVA should help patients on a breathing machine, we do not yet know if it will get them off ventilators faster.

The only way to find out if NAVA helps us use the breathing machine is to do a trial. If we show that NAVA does help get people off breathing machines more quickly, we might save lives, help make intensive care treatments more comfortable, and save the NHS money.

Patients, families and staff have all told us that they think this trial is really important.

In total, we hope to include 900 patients in 40 intensive care units from across the UK in this trial.

In the trial, **half** of the patients will have the usual breathing machine **but with NAVA added,** and **half** will have the usual breathing machine **without NAVA (usual care).**

What is expected from me & what happens now?

Although NAVA is **not experimental**, we still think it is important to speak to you to check whether you think your relative/friend would like to remain in the UK NAVA trial.

We will ask you to sign a **consultee declaration form**, that documents that you agree that we continue with the trial **until we are able to ask your relative/friend themselves.**

Sometimes relatives and friends will also need to be consulted because the patient has a learning difficulty or mental health disorder that will make direct discussions with them difficult or inappropriate. Here, we want to check that we are doing the right thing with someone who knows the patient well.

What happens if I say YES?

We will give you a copy of the signed consultee form to keep.
We will give information to your friend/relative and ask their opinion when they are well enough, including consent to continue in the trial. We will provide them with contact details should they need help or support at any stage in the trial.
We will continue to use the breathing machine with/without NAVA, according to the treatment they were randomly assigned by a computer programme in the trial.
All other parts of care will be identical.
We will always act in the best interests of your relative/friend.
We will collect some simple information such as age, ethnicity and past medical history so that we can understand how different groups of patients might be helped by NAVA.
We also plan to collect some information about them (name/address/date of birth/NHS number) and their recovery from hospital records and national databases.
After leaving the hospital, your relative/friend will be sent a **questionnaire** two and six months after their hospital discharge asking about their overall wellbeing and quality of life. Each questionnaire will take approximately **5-10 minutes** to complete.
We will share your relative/friend's name, email address, and phone number with a third-party company (called Twilio) in order to send them the questionnaires by text message, email or post. We may also get in touch with your relative/friend by text message, email or telephone if we have any queries about their questionnaire or if we have any updates related to the study.
The University of Warwick will keep this information **safe and private**. When the trial is finished, the university and the hospital that treated your relative/friend will keep the information for 5 years and then delete anything that links the information to them. Only staff members who are working on this trial and need to see it will be able to access their personal data.

The University of Warwick is currently leading several trials looking at how we treat patients with breathing problems. This family of trials is called the 'Confederation of Respiratory Critical Care Trials' or '**CoReCCT**'. If you are taking part in **other** trials within CoReCCT, you will not need to complete questionnaires for each trial – you will only be asked to complete each questionnaire **once**.

If you say yes today, you can change your mind at any time, without giving us a reason. You do not have to say yes to your relative/friend taking part. Their care won't be affected in any way. If they don't want to complete the questionnaires, they can tell the researchers at their hospital. If they do not want us to collect information about their recovery, they can tell us. We would normally keep and use all the information already collected about them.

What happens if I say NO?

If you decide that your relative/friend **would not** want to be part of the trial (to the best of your knowledge), no further trial activities like questionnaires/follow-up will occur.

We will ask whether we can keep a small amount of data that we have collected already.

Benefits of taking part

We can't promise there will be any benefit to taking part for your relative/friend, however we hope that this research will help patients in the future who need help with their breathing on critical care units.

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

Risk of taking part

The risk of harm of taking part in this trial isn't thought to be any higher than the usual care patients get, because NAVA is already used in the NHS. We just don't know if it is **better** than usual care.

What if there is a problem?

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

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
Tel: 02476 575733
Email: researchgovernance@warwick.ac.uk

In this research trial we will use information from your friend/relative, their GP, their medical records, and healthcare databases such as NHS England. We will only use information that we need for the trial.

Everyone involved in this trial will keep their data safe and secure. We will also follow all privacy rules.

At the end of the trial 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 your relative/friend is from the reports we write.

For details on how data is used and kept safe, visit https:warwick.ac.uk/nava/public or scan the QR code at the end of this leaflet. If you prefer a printed copy please ask a member of staff.

The University of Warwick will provide indemnity for this trial. If your family member/friend is harmed due to someone's negligence, they may have grounds for legal action which they may have to pay for. NHS bodies may also be liable if they 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 has reviewed this research?

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. This committee is there to protect your interests. This trial has been reviewed and been approved by Wales REC 2.

This research is funded by the National Institute of Health and Care Research. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Further information

For more information, please contact the NAVA Trial Manager at Warwick University:
Email: NAVA@warwick.ac.uk

An online version of this information sheet can be accessed by scanning the below QR code or via: https:warwick.ac.uk/nava/public

Thank you for taking the time to read this leaflet and consider your relative/friend's potential participation in the UK NAVA trial.

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