Patient Information Sheet

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 have been given this leaflet because you needed to be put on a breathing machine (called a ventilator) in intensive care. Whilst you were very ill, you were enrolled into a trial called **UK NAVA**. This trial is looking at the **potential benefit** of **adding** an extra system called **NAVA** to the usual way of using a breathing machine. It is being done in 900 patients on 40 intensive care units in the UK.
- Because you could not make the decision yourself, where possible we either asked a relative/friend or an independent consultant whether they thought you would agree to be part of the trial.
- The trial does **not** use any experimental treatment. NAVA is already an approved treatment. We hope this helped them with making this difficult decision.
- We also know that the trial is strongly supported by independent patients, relatives, and staff, who helped us put this research together

What is NAVA and how does the trial work?

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 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. This means NAVA should not need any different procedures compared to usual care.

In the trial, **half** of the patients will have ventilation **with NAVA**, and **half** will have ventilation **without** ('usual care'). Which group you were in was decided randomly by a computer programme. If you'd like to know more, please let us know.

If you have been off the breathing machine for more than 48 hours then the trial treatment has finished.

If you are still on a ventilator, then the doctors and nurses will be giving you the treatment they think is now best. This may or may not include NAVA.

What happens now?

We would like to ask you to sign a consent form to tell us what you now wish to do. You will already have had the breathing machine treatment, but it is important for us to ask your permission to confirm you are happy to be followed-up.
To see how well you're recovering, we would like to send you a questionnaire at 2 & 6 months after your ventilation. These will take 5-10 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 (called Twilio) to send you the questionnaires by text message, email or post. We may 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 trial.
We also plan to collect information about you (name/address/date of birth/NHS number) and your recovery from hospital records and national databases.

The University of Warwick is collecting all the information from the trial, and we will keep it safe and private. When the trial is finished, the university and the hospital that treated you will keep the information for 5 years and then delete anything that links the information to you. Only staff members who are working on this trial and need to see it will be able to access your personal data.

The University of Warwick is currently leading several trials looking at how we treat patients with breathing problems. This group 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 study – 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 take part. Your care won't be affected in any way. If you don't want to complete the questionnaires, just tell the researchers at your hospital. If you do not want us to collect information about your recovery, please tell us. We would normally keep and use all the information already collected about you.

Benefits of taking part

Doctors don't know whether using NAVA is always better, and this is why we're doing a trial to find out. We can't promise there will be any benefit to taking part, 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 you for your time in completing the follow-up questionnaires at two-months and six-months, we will give you a small monetary gift voucher alongside each questionnaire.

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 you would get, because NAVA is already used in the NHS.

Because the trial involves completing questionnaires, there's a risk you may find some questions about your recovery upsetting to answer. Our trained research staff can talk to you about any feelings you may have, and there are contact details listed further down if you need to get in touch with someone.

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: **[insert local Patient Advice and Liaison Service details or relevant local contact]**

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

The University of Warwick will provide indemnity for this trial. 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.

In this research trial we will use information from you, your GP, your 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 your 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 you are 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.

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 trial.

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 study 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 information and for considering taking part in this trial.

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