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A randomised trial comparing two current ventilation treatments in the Intensive Care Unit: The UK NAVA Trial

Submission date
07/10/2024

Recruitment status
Recruiting

Registration date
09/12/2024

Overall study status
Ongoing

Last Edited
04/09/2025

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Around half of all patients in critical care need help from a breathing machine (ventilator) to maintain oxygen levels. Although they may be life-saving, breathing machines can cause damage to diseased lungs and make chest infections more likely. NAVA stands for Neurally Adjusted Ventilatory Assist and is a type of technology which allows doctors to see how well the ventilator is working for each patient. NAVA technology can tell doctors how much a patient is trying to breathe on their own and set the ventilator settings to work best with them, depending on how their body responds. This might help patients get better quicker and spend less time on a ventilator, but a study is required to find out. This trial aims to find out if using NAVA technology helps patients with diseased lungs spend less time on a ventilator compared to the usual way breathing support is given in critical care. The researchers also want to know if NAVA technology saves more lives, improves quality of life, and saves the NHS money by helping people leave ICU sooner.

Who can participate?
Patients aged 18 years or more admitted to an ICU in the UK who are expected to have breathing support for at least 2 days and have a clinical reason why reducing the time on a ventilator might take longer or be more difficult than usual

What does the study involve?
Participants will be assigned by chance (randomised) to one of two groups.
1. NAVA Technology: Participants will be given ventilation with NAVA technology.
2. Usual care: The ventilator will be set as usual by the intensive care team.
There will be no other changes to care delivered by the intensive care team for patients in both the NAVA and the usual care group.
Participants, the research team, or the intensive care team will not be able to choose which group each participant is enrolled into. This is decided by a computer at random, just like tossing a coin or drawing lots. The research team will collect information about the care the participants receive while in intensive care including how the ventilator is used, how long they need ventilation, and how long they stay in intensive care. The research team will collect the

participants' personal information such as age, ethnicity, sex and past medical conditions before coming to intensive care as this helps them to understand the effect of NAVA on different groups of people.
After leaving the hospital, participants will be sent a questionnaire 2 and 6 months after hospital discharge asking about their overall wellbeing and quality of life. Each questionnaire will take about 5 to 10 minutes to complete. If needed, someone can complete them on the participant's behalf. The researchers will share the participant's name, email address, and phone number with a third-party company to send them the questionnaires by text message or email. They may also get in touch with participants by text message or email if we have any queries about their questionnaire or if we have any updates related to the trial.

What are the possible benefits and risks of participating?
Doctors don't know whether using NAVA is always better, and this is why we're doing a trial to find out. It is hoped that this research will help patients in the future who need help with their breathing in intensive care units. The risk of harm of taking part in this trial isn't thought to be any higher than usual care, because NAVA is already used in the NHS. There is no payment for taking part in this study. However, to thank participants for their time in completing the follow-up questionnaires at 2 and 6 months, they will be given a small monetary gift voucher alongside each questionnaire.
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 participants are taking part in other studies within CoReCCT, they will not need to complete questionnaires for each study. Participants will only be asked to complete the questionnaires once and will receive one voucher with each questionnaire.

Where is the study run from?
Warwick University in partnership with NHS hospitals across the UK

When is the study starting and how long is it expected to run for?
May 2024 to May 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme

Who is the main contact?
NAVA trial manager, NAVA@warwick.ac.uk

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335630

Protocol serial number

CPMS 62936, NIHR155119

Study information

Scientific Title
Neurally Adjusted Ventilatory Assist (NAVA) compared to conventional ventilation for patients at risk of difficult or prolonged weaning from invasive mechanical ventilation

Acronym
UK NAVA

Study objectives
For invasively ventilated adults at risk of prolonged weaning from ventilatory support, the use of Neurally Adjusted Ventilatory Assist (NAVA) technology in addition to standard care reduces the duration of mechanical ventilation when compared to standard care alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/10/2024, Wales REC 2 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922941119; Wales.REC2@wales.nhs.uk), ref: 24/WA/0128

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Use of Neurally Adjusted Ventilatory Assist (NAVA) technology for invasively ventilated adults at risk of prolonged weaning from ventilatory support

Interventions
The study will compare NAVA Technology to conventional IMV. NAVA technology uses a specialised nasogastric/orogastric tube (NAVA catheter) to obtain the electrical activity of the diaphragm (EDi) muscle, which is a reliable index of the patient's respiratory drive. Once the NAVA catheter is placed and connected, the EDi is always visible to clinicians, allowing optimisation of ventilator settings in any mode. When the NAVA mode is active, the ventilator triggers, cycles and adjusts support in synchrony and proportion to the EDi.

There are three components of the UK NAVA trial intervention:
EDi signal acquisition and optimisation
NAVA monitoring
The NAVA mode: proportional and synchronous pressure support, controlled by the EDi signal.
The intervention (NAVA technology or control) will continue until one of the following criteria is

met:
• 28 days after randomisation
• Successful unassisted breathing
• Study intervention-related serious adverse event
• Death or discontinuation of active treatment
• The person giving consent requests discontinuation of the intervention
• NAVA equipment unavailable

Intervention Type
Procedure/Surgery

Primary outcome(s)
Duration of mechanical ventilation, measured by time from randomisation to first successful unassisted breathing or death

Key secondary outcome(s))
1. All-cause mortality, measured by survival at 2 and months
2. Time to first extubation, measured by time from randomisation to first successful extubation, up until ICU discharge
3. Reintubation, reintubation rates measured from randomisation up until ICU discharge
4. Use of Non-invasive ventilation, measured from randomisation up until ICU discharge
5. ICU and hospital length stay, measured by time from randomisation until ICU and hospital discharge
6. Serious adverse events, reportable from time of randomisation up until hospital discharge
7. Health-related Quality of Life and health care resource use, measured by EQ5D and resource use questionnaire at 2 and 6 months

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Receiving invasive mechanical ventilation
3. Expected to stay on invasive mechanical ventilation for ≥ 48hrs
4. Any clinical risk factor for difficult or prolonged weaning from invasive ventilation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 04/08/2025:
1. Death or treatment withdrawal imminent within 48 hours
2. Contraindication to nasogastric or orogastric tube insertion, such as upper airway or oesophageal trauma, bleeding or risk of bleeding due to recent surgery (e.g., oesophageal surgery), oesophageal varices and/or portal hypertension, and skull base fracture
3. A temporary or permanent cardiac pacemaker (potential impact on the EDi signal)
4. Phrenic nerve injury, Myasthenia Gravis or Guillain Barre Syndrome (potential impact on the EDi signal)
5. Severe central neurologic disorder causing elevated intracranial pressure, impaired control of breathing, or requiring neuroprotective ventilation (e.g. severe traumatic brain injury, refractory status epilepticus)
6. Known or suspected, severe or progressive neuromuscular disorder likely to result in prolonged or chronic ventilator dependence (e.g., Motor Neuron Disease, Duchenne Muscular Dystrophy, Amyotrophic Lateral Sclerosis, Multiple Sclerosis, spinal cord injury above C6, Kyphoscoliosis, or other restrictive disorder).
7. Severe, end-stage, irreversible respiratory or cardiac disease with referral to a long-term weaning unit for likely chronic ventilator dependence, or referral to palliative care (e.g. severe irreversible pulmonary fibrosis or interstitial lung disease)
8. Home ventilation prior to ICU admission, excluding nocturnal CPAP
9. Previous participation in the UK NAVA trial.

Previous exclusion criteria:
1. Death or treatment withdrawal imminent within 48 hours
2. Contraindication to NG or orogastric tube insertion, such as upper airway or oesophageal trauma, bleeding or risk of bleeding due to recent surgery, oesophageal varices or portal hypertension, and skull base fracture
3. An active cardiac pacemaker or phrenic nerve injury, due to their impact on the EDi signal.
4. Severe central neurologic disorder (e.g., traumatic brain injury, haemorrhage, stroke, tumour) causing elevated intracranial pressure, or impaired control of breathing, or requiring specific ventilator adjustments (i.e., to attain specific CO2 target) or requiring neurosurgical intervention
5. Known or suspected severe or progressive neuromuscular disorder likely to result in prolonged or chronic ventilator dependence (e.g., Motor Neuron Disease, Duchenne Muscular Dystrophy, Amyotrophic Lateral Sclerosis, Multiple Sclerosis, high spinal cord injury, Kyphoscoliosis, or other restrictive disorder).
6. Severe, end-stage, irreversible respiratory or cardiac disease likely to result in chronic ventilator dependence (e.g. interstitial lung disease, pulmonary fibrosis, cardiomyopathy, valvulopathy)
7. Continuous therapeutic neuromuscular paralysis
8. Home ventilation prior to ICU admission, excluding nocturnal CPAP.
9. Previous participation in the UK NAVA trial.

Date of first enrolment
11/08/2025

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

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Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes