UK NAVA randomisation flowchart

Inclusion Criteria:

- Age 18 years or over
- Receiving IMV
- Expected to stay on IMV for ≥ 48hrs
- Any acute and/or chronic clinical risk factor for difficult or prolonged weaning from invasive ventilation*

*For guidance, acute clinical risk factors would include pneumonia, ARDS, septic shock, multiple organ failure, acute pancreatitis. Chronic risk factors would include history of heart failure, COPD, obesity. Patients should not be included if they are solely being kept ventilated whilst awaiting imaging, a procedure, after drug overdose or awaiting a test result. Further guidance is provided during training.

Exclusion Criteria

- Death or treatment withdrawal imminent within 48 hours
- 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
- A temporary or permanent cardiac pacemaker (potential impact on the EDi signal)
- Phrenic nerve injury, Myasthenia Gravis or Guillain Barre Syndrome (potential impact on the EDi signal)
- 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)
- 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).
- 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)
- Home ventilation prior to ICU admission, excluding nocturnal CPAP
- Previous participation in the UK NAVA trial

Cross check inclusion and exclusion criteria, is the patient eligible for the UK NAVA trial?

Yes → Is there time to approach a consultee? If not then use deferred consent, which should be confirmed and documented by an appropriate clinician.

Unsure → Is there time to approach a consultee? If not then use deferred consent, which should be confirmed and documented by an appropriate clinician.

No → Continue to give patient care as per clinical plan.

Appropriate Clinicians:

Unable to find appropriate clinician/need support → Contact Research team for advice. Handover to day team or email _____if out of hours.

Eligibility confirmed and documented → **RANDOMISE** using the QR code below

Randomised to NAVA technology arm → **NAVA technology intervention**

Follow UK NAVA QuickGuide for NAVA Catheter insertion and setting up NAVA Monitoring and Mode.
Contact Research Team for support.

Randomised to Standard care → **Standard care**

Do NOT insert NAVA Catheter. Give patient care as per clinical plan and standard care.
Contact research team for support.

Refer to participant recruitment checklist ↔ Approach consultee or participant for consent as soon as possible

Useful Contacts and online resources:
UK NAVA phone number: 02476151665
UK NAVA email: nava@warwick.ac.uk
Website: www.uknava.com