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PROTECT Airways: a research study to find out if an alternative airway system is better than standard of care for patients connected to a breathing machine

Submission date
21/02/2025

Recruitment status
Recruiting

Registration date
21/02/2025

Overall study status
Ongoing

Last Edited
21/02/2025

Condition category
Other

[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
A breathing tube is the pathway through which air flows into the lungs. Intensive care units (ICU) are specialist hospital wards that provide treatment and monitoring for people who are very ill. Close to 184,000 patients annually are admitted to NHS ICUs and 33% require help with their breathing, using a machine which is called invasive mechanical ventilation. Treatment involves placing a plastic tube through the mouth into the windpipe and attaching the person to a breathing machine (ventilator). A serious complication of this life-saving treatment is a chest infection or ventilator-associated pneumonia (VAP) which affects 20% of people on ventilators. It occurs when mucus, a jelly-like liquid that lines your lungs, throat, mouth, nose, that is infected drips down the back of the throat past the plastic tube into the lungs. Whilst VAP can be treated with antibiotics, some people will die and others will spend much longer on a ventilator.
The alternative airway system aims to improve the windpipe seal and reduce the risk of infected mucus passing down into the lung, by maintaining the inflation of the protective cuff. Patient studies suggest this system is safe and effective at removing mucus and preventing lung infection. Some hospitals are using the alternative airway system. However, we do not know if the positive findings seen in a few hospitals would also be seen in the wider NHS, and whether the new tube is good value for money, resulting in benefits to patients. The National Institute for Health and Care Excellence (NICE), the organisation that provides guidance for health and care practitioners to deliver the best care, has therefore recommended a large-scale research study to see if this equipment is needed.

Who can participate?
Adult (aged 18 years and over), needing invasive mechanical ventilation, likely to remain on a breathing machine for at least 24 hours following study entry.

What does the study involve?
Participants will be assigned by chance (known as randomisation) to one of two groups:
1. Alternative airway system: This is similar to the standard care tube, and in addition has a

system to ensure the seal to the patient is maintained and has multiple ports to remove secretions (fluids).
2. Standard care: The tube usually used by the hospital will be used.
There will be no other changes to care given to patients in both the alternative airway system and the standard care group.
The participant and the hospital team will not be able to choose which group they are placed in. This is decided by a computer at random (known as randomisation). This process ensures there is an equal chance of being placed in either group and is the best way to ensure that there is a fair comparison between both tubes.
The research team will collect information about care the participant receives while in hospital including how the ventilator is used, how long they need the ventilator, and how long they stay in hospital. The research team will collect personal information such as age, ethnicity, sex and past medical conditions before coming to critical care as this helps to understand the effect of the tube on different groups of people.
The participant will be sent a questionnaire 2 and 6 months after entering the study asking about overall wellbeing and any healthcare used.

What are the possible benefits and risks of participating?
As this is a research study, the participant may or may not experience a direct benefit. However, the findings of the study may help people needing a breathing machine in critical care in the future.
The alternative airway system is approved for use in the NHS and is already used as part of standard care in some hospitals. Therefore, the researchers do not anticipate any serious risk specific to being in the alternative airway system group. However, all patients who are very sick and need a breathing machine are at risk of complications such as damage to the lungs or needing the tube to be put back in after it is removed due to ongoing problems with breathing. Some very sick patients may even die.

Where is the study run from?
The study is sponsored by the University of Warwick and is coordinated by the Warwick Clinical Trials Unit 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 June 2029

Who is funding the study?
The National Institute for Health Research, Health Technology Assessment (NIHR156500) (UK)

Who is the main contact?
PROTECT Airways Trial Manager, protectairways@warwick.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

335630

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62932, Grant Code: NIHR156500

Study information

Scientific Title
The clinical and cost-effectiveness of advanced airways protection device versus conventional endotracheal tubes in intensive care unit patients requiring mechanical ventilation: a multi-centre, pragmatic randomised clinical trial

Acronym
PROTECT Airways

Study objectives
To conduct a UK-wide multi-centre, open-label, pragmatic, individually randomised, parallel-group trial and economic evaluation to determine the clinical and cost-effectiveness of an advanced airways protection device versus conventional endotracheal tubes (with and without basic subglottic manual suction and standard cuff) in patients with respiratory failure requiring mechanical ventilation.

Aim: In mechanically ventilated adults in intensive care units (ICU), does an advanced airways protection device reduce the duration of invasive mechanical ventilation and is it cost-effective?

Participant population: Tracheal intubated adults (≥18 years) who are in ICU and are receiving invasive mechanical ventilation and are likely to remain ventilated for at least 24 hours post-randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/10/2024, Wales Research Ethics Committee 2 Cardiff (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road, East Cardiff, CF11 9AB, UK; +44 (0)2922941119, +44 (0)2922 940959; Wales.REC2@wales.nhs.uk), ref: 24/WA/0128

Study design
Randomized; Interventional; Design type: Treatment, Device, Complex Intervention, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Intensive care unit patients requiring mechanical ventilation

Interventions
Intervention: a CE-marked advanced airways protection device (Venner PneuX™)
Control: standard of care endotracheal tube used at hospital.

The randomisation system will be a secure web-based and allocation concealed system developed centrally by the programming team at Warwick Clinical Trials Unit. Randomisation will be done using a computerised algorithm using the minimisation method for randomising patients. The randomisation sequence will be created, stratified by hospital site, if the patient is intubated prior to randomisation and prior enrolment into the Awake Prone trial (ISRCTN63784375). Patients will be randomised, in a ratio of 1:1.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Venner PneuX™

Primary outcome measure
Duration of mechanical ventilation in days as measured from time from randomisation to first successful unassisted breathing, measured using data collected from medical records

Secondary outcome measures
1. Ventilator-associated pneumonia (VAP), diagnosed by treating clinician with the commencement of antibiotics from randomisation up to ICU discharge, using data collected from medical records.
2. Hospital-acquired pneumonia (HAP) following extubation: clinician diagnosis and commencement of antibiotics from randomisation up to ICU discharge, using data collected from medical records.
3. Reportable serious adverse events that occur between randomisation and time of hospital discharge, using data collected from medical records.
4. Pre-specified adverse events that occur between intubation and time of ICU discharge, using data collected from medical records.
5. Costs associated with the use of NHS & personal social services (PSS) resources arising during

the hospital stay and after hospital discharge; personal expenditures (out-of-pocket costs) incurred by patients after hospital discharge. Collected from participants via questionnaire at 2 and 6 months following randomisation.
6. Health-related quality of life measured using a widely used and recommended preference-based quality of life instrument (EQ-5D-5L) collected from participants via questionnaire at 2 and 6 months following randomisation

Overall study start date
01/05/2024

Completion date
30/06/2029

Eligibility

Key inclusion criteria
1. Adult (age ≥18 years)
2. Need for invasive mechanical ventilation
3. Likely to remain ventilated for at least 24 hours post-randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2194; UK Sample Size: 2194

Key exclusion criteria
1. Treatment withdrawal anticipated over the next 24 hours
2. Presence of tracheostomy at screening
3. Intubated for more than 24 hours prior to randomisation

Date of first enrolment
01/03/2025

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Conquest Hospital
The Ridge
St. Leonards-on-sea
United Kingdom
TN37 7RD

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

Study participating centre
Manchester Royal Infirmary
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
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M13 9WL

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
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ME7 5NY

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
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United Kingdom
SA6 6NL

Study participating centre
Royal Oldham Hospital
Royal Oldham Hospital
Rochdale Road
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OL1 2JH

Study participating centre
St James' s University Hospital
Beckett Street
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LS9 7TF

Study participating centre
University Hospital of North Tees
Hardwick Road
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TS19 8PE

Study participating centre
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L9 7AL

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Study participating centre
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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2029

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?
Participant information sheet	version 1.0		21/02/2025	No	Yes