Awake prone positioning in non-intubated adults with respiratory failure

Submission date	Recruitment status Recruiting	[X] Prospectively registered		
01/08/2024		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/08/2024	Ongoing	Results		
Last Edited 12/09/2025	Condition category Respiratory	Individual participant data		
		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

Every year, over 60,000 adults in the UK go on a ventilator on an intensive care unit. A common reason for going on a ventilator is breathing conditions, such as pneumonia. Going on a ventilator is life-saving. However, some people that go on a ventilator do unfortunately die and many patients that do survive report long-term effects on their quality of life. For this reason, avoiding the need to go on a ventilator, when safe to do so, is important to patients and the healthcare teams looking after them. We know that for patients with COVID-19, lying them on their tummy (awake prone positioning), when they require high amounts of oxygen reduces the likelihood that they will need a ventilator. We don't currently know whether this will work in patients without COVID-19. Some treatments work well in COVID-19, but not in patients requiring oxygen for conditions, such as pneumonia. We know from treating patients during the COVID-19 pandemic and feedback from patient partners that lying on your tummy can be uncomfortable. It is important that we undertake research to find out if awake prone positioning is effective in patients without COVID-19. For patients in hospital requiring high amounts of oxygen, we want to find out if lying them on their tummy, rather than lying on their back/ sitting up reduces the likelihood that they will need to go on a ventilator on an intensive care unit.

Who can participate?

Patients aged over 18 years in hospital with respiratory problems who are needing at least 40% oxygen

What does the study involve?

Participants will be randomly allocated to one of two groups. In the first group, the researchers will position patients on their front (awake prone positioning) for at least 8 hours per day for up to 5 days. In the second group, patients will receive standard care, where they will be positioned sat up in bed.

The researchers will follow up study participants for 6 months. They will record how many patients have survived and how well they have recovered using some brief questionnaires. They will also see how long people spend on intensive care units and in hospital.

What are the possible benefits and risks of participating?

During the COVID-19 pandemic, many patients in hospital received awake prone positioning. The

key risks to awake prone positioning are discomfort and the possibility of dislodging medical devices (such as intravenous lines) when transferring to someone's front.

Where is the study run from?
University of Warwick Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for? January 2024 to December 2027

Who is funding the study?

The National Institute for Health Research (UK) Health Technology Assessment Programme (UK)

Who is the main contact?

Dr Keith Couper, awakeprone@warwick.ac.uk

Contact information

Type(s)

Scientific, Principal investigator

Contact name

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Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

335630

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 62433, NIHR154796, IRAS 335630

Study information

Scientific Title

CoReCCT: The Awake Prone Study: Awake prone positioning in patients with acute hypoxaemic respiratory failure not due to COVID-19: A randomised controlled trial

Acronym

CoReCCT

Study objectives

The primary objective of this trial is to evaluate the clinical effectiveness of awake prone positioning in non-intubated adults with acute hypoxaemic respiratory failure not due to COVID-19, measured by our primary outcome of tracheal intubation within 30 days.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/07/2024, Wales REC 2 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2922941119, +44 (0)2922 940971, +44 (0) 2922 940959; Wales.REC2@wales.nhs.uk), ref: 24/WA/0128

Study design

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

Primary study design

Interventional

Study type(s)

Health condition(s) or problem(s) studied

Acute hypoxaemic respiratory failure not due to COVID-19

Interventions

In the intervention arm, participants will receive awake prone positioning over a maximum of 5 days/120 hours from randomisation. The target daily duration for awake prone positioning is \geq 8 hours per 24-hour period. This may be achieved through a single long period of awake prone positioning or several shorter periods. The researchers expect any shorter period to last at least 1 hour. Each day, they will record the amount of time that an individual has spent in the awake prone position (full-prone or 3/4 prone) in the preceding 24 hours.

Participants will lie in a prone position as long and frequently as feasible, as soon as possible after randomisation. The intervention will continue until one of the following criteria is met:

- 1. 120 hours from randomisation
- 2. Tracheal intubation
- 3. Participant recovery
- 4. Participant decision to stop intervention
- 5. Development of contraindication to awake prone positioning
- 6. Participant transferred to a care setting where intervention could not be delivered
- 7. Participant transferred to another hospital

In the control group, participants will receive standard care, which does not include awake prone positioning.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

The incidence of tracheal intubation within 30 days of randomisation, measured using hospital records. This does not include tracheal intubation where it is used only to facilitate an operation or procedure.

Key secondary outcome(s))

All secondary outcomes are measured to hospital discharge using hospital records unless specified:

- 1. Length of critical care stay (days), from randomisation
- 2. Length of hospital stay (days), from randomisation
- 3. Time to tracheal intubation (days)
- 4. Time to admission to critical care (hours/days)
- 5. Duration of non-invasive respiratory support (days)
- 6. New requirement for non-invasive respiratory support (yes/no)
- 7. Duration of mechanical ventilation during hospital stay (previously invasive ventilation)
- 8. Mortality, measured at hospital discharge, 2 months, and 6 months
- 9. Health-related quality of life measured using the EQ-5D-5L at 2 and 6 months
- 10. Pre-specified complications that occur between randomisation and 5 days (pressure ulcer /skin breakdown, dislodgement of central venous catheter, dislodgement of arterial catheter,

dislodgement of peripheral venous catheter, dislodgement of urinary catheter, dislodgement of any other medical device, nausea requiring new treatment with anti-emetics, vomiting)

Completion date

31/12/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 28/07/2025:

- 1. Adult (age >18 years) hospitalised patient who is not intubated
- 2. Acute hypoxaemic respiratory failure which has required treatment with 40% oxygen or more for at least 1 hour
- 3. Deemed suitable for tracheal intubation in the event of physiological deterioration

Previous inclusion criteria:

- 1. Adult (age >18 years) hospitalised patient who is not intubated
- 2. Acute hypoxaemic respiratory failure, defined as sustained SpO2 ≤94% whilst receiving ≥40% supplemental oxygen
- 3. Deemed suitable for tracheal intubation in the event of physiological deterioration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. Hypoxaemia fully explained by acute pulmonary oedema due to heart failure
- 2. Patient unwilling to attempt awake prone positioning
- 3. Contraindication to awake prone positioning
- 4. COVID-19 pneumonitis as primary cause of respiratory failure
- 5. Invasive mechanical ventilation during current hospital admission (except where provided only to facilitate a procedure or operation)

Date of first enrolment

03/02/2025

Date of final enrolment

28/02/2027

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Wales

Study participating centre Arrow Park Hospital

Arrowe Park Hospital Arrowe Park Road Wirral United Kingdom CH49 5PE

Study participating centre Hartington Unit

Chesterfield Royal Hospital Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre Fairfield General Hospital

Rochdale Old Road Bury United Kingdom BL9 7TD

Study participating centre Ipswich Hospital

Heath Road Ipswich United Kingdom IP4 5PD

Study participating centre James Paget University Hospital

Lowestoft Road Gorleston Great Yarmouth United Kingdom NR31 6LA

Study participating centre Kettering General Hospital Laboratory

Kettering General Hospital Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre Kingston Hospital

Galsworthy Road Kingston upon Thames United Kingdom KT2 7QB

Study participating centre Leighton Hospital

Leighton Crewe United Kingdom CW1 4QJ

Study participating centre Morriston Hospital

Heol Maes Eglwys Cwmrhydyceirw Swansea United Kingdom SA6 6NL

Study participating centre

Northampton

Northampton General Hospital Cliftonville Northampton United Kingdom NN1 5BD

Study participating centre Stepping Hill Hospital

Poplar Grove Stockport United Kingdom SK2 7JE

Study participating centre Tameside General Hospital

Fountain Street Ashton-under-lyne United Kingdom OL6 9RW

Study participating centre Bedford Hospital

Icash Bedford Hospital Kempston Road Bedford United Kingdom MK42 9DJ

Study participating centre Bristol Royal Infirmary

Marlborough Street Bristol United Kingdom BS2 8HW

Study participating centre Glenfield General Hospital

Groby Road

Leicester United Kingdom LE3 9QP

Study participating centre Good Hope Hospital

Rectory Road Sutton Coldfield United Kingdom B75 7RR

Study participating centre Heartlands Hospital

Bordesley Green East Bordesley Green Birmingham United Kingdom B9 5ST

Study participating centre Newham General Hospital

Glen Road London United Kingdom E13 8SL

Study participating centre Pinderfields General Hospital

Aberford Road Wakefield United Kingdom WF1 4DG

Study participating centre Poole Hospital

Longfleet Road Poole United Kingdom BH15 2JB

Study participating centre Princess Royal Hospital

Apley Castle Grainger Drive Apley Telford United Kingdom TF1 6TF

Study participating centre Queen Elizabeth Hospital Lewisham

Stadium Road London United Kingdom SE18 4QH

Study participating centre Queen Elizabeth Hospital

Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2GW

Study participating centre Queen Elizabeth The Queen Mother

Ramsgate Road Margate Kent United Kingdom CT9 4AN

Study participating centre Rotherham District General Hospital

Moorgate Road Rotherham United Kingdom S60 2UD

Study participating centre

Royal Oldham Hospital

Rochdale Road Oldham United Kingdom OL1 2JH

Study participating centre Royal Sussex Hospital

Eastern Rd
Brighton and Hove
Brighton
United Kingdom
BN2 5BE

Study participating centre Ulster Hospital

Upper Newtownards Rd Dundonald Belfast United Kingdom BT16 1RH

Study participating centre Warrington Hospital (site)

Warrington Hospital Lovely Lane Warrington United Kingdom WA5 1QG

Study participating centre The Royal Glamorgan Hospital

Ynysmaerdy Pontyclun United Kingdom CF72 8XR

Study participating centre St Georges Hospital Blackshaw Road

London

United Kingdom SW17 0QT

Study participating centre Leeds General Infirmary

Great George Street Leeds United Kingdom LS1 3EX

Study participating centre University Hospital Lewisham

Lewisham High Street London United Kingdom SE13 6LH

Study participating centre Watford General Hospital

60 Vicarage Road Watford United Kingdom WD18 0HB

Study participating centre Weston General Hospital

Grange Road Uphill Weston-super-mare United Kingdom BS23 4TQ

Study participating centre Ysbyty Glan Clwyd

Glan Clwyd Hospital Rhuddlan Road Bodelwyddan Rhyl United Kingdom LL18 5UJ

Study participating centre Gloucestershire Royal Hospital

Great Western Road Gloucester United Kingdom GL1 3NN

Study participating centre Milton Keynes University Hospital

Milton Keynes Hospital Standing Way Eaglestone Milton Keynes United Kingdom MK6 5LD

Study participating centre Scarborough Hospital

Woodlands Drive Scarborough United Kingdom YO12 6QL

Study participating centre St James' S University Hospital

Beckett Street Leeds United Kingdom LS9 7TF

Study participating centre William Harvey Hospital

Kennington Road Willesborough Ashford United Kingdom TN24 0LZ

Study participating centre

York District Hospital

Wigginton Road York United Kingdom YO31 8HE

Sponsor information

Organisation

University of Warwick

ROR

https://ror.org/01a77tt86

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

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?
Participant information sheet	version 2.0	11/06/2024	20/08/2024	No	Yes
Participant information sheet	version 3.0	20/09/2024	14/03/2025	No	Yes
Participant information sheet	version 4.0	31/03/2025	23/05/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	13/06/2024	20/08/2024	No	No

<u>Protocol file</u>	version 3.0	20/09/2024	14/03/2025 No	No
Protocol file	version 4.0	07/04/2025	23/05/2025 No	No
Protocol file	version 5.0	03/07/2025	28/07/2025 No	No