ISRCTN63784375 https://doi.org/10.1186/ISRCTN63784375

Awake prone positioning in non-intubated adults with respiratory failure

Submission date 01/08/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 20/08/2024	**Overall study status** Ongoing	
Last Edited 26/06/2025	**Condition category** Respiratory	

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

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335630

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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
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 ≥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 measure
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.

Secondary outcome measures
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)

Overall study start date
01/01/2024

Completion date
31/12/2027

Eligibility

Key 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 event of physiological deterioration

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1708; UK Sample Size: 1708

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
England

Northern Ireland

United Kingdom

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
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Rhyl

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LL18 5UJ

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University of Warwick

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

Results and Publications

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

Intention to publish date
31/12/2028

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
Protocol file	version 2.0	13/06/2024	20/08/2024	No	No
Participant information sheet	version 3.0	20/09/2024	14/03/2025	No	Yes
Protocol file	version 3.0	20/09/2024	14/03/2025	No	No
Participant information sheet	version 4.0	31/03/2025	23/05/2025	No	Yes
Protocol file	version 4.0	07/04/2025	23/05/2025	No	No