AWAKE PRONE

Frequently Asked Questions

Set Up

Is there a minimum recruitment target?

Our recruitment target is based on 60 sites recruiting 1.25 patients a month.

Are there multiple accruals if a patient participates in more than one CoReCCT domain (trial)?

Yes. There is one accrual per CoReCCT trial. Each trial has its own CPMS ID. Recruitment uploads, however, will be managed by Warwick CTU. Sites only need to mark themselves as 'open to recruitment' on their local portfolio management system.

What database will the study be using?

A bespoke Warwick CTU built database. This will consist of Core and domain specific parts. The Core Database will house data and CRFs shared across CoReCCT domains; the domain specific database will house data and CRFs specific to each domain. Database access will be controlled by the domain specific delegation logs you appear on.

Screening & Eligibility

Who confirms eligibility?

Eligibility can be confirmed by anyone that is suitably trained and experienced and who has been delegated responsibility to undertake this role by the PI.

Which patients should be entered on the screening log?

Please record details of patients that meet all the inclusion criteria, and who meet one or more of the exclusion criteria (making them ineligible). On the log, select which of the exclusion criteria they met. Patients that are randomised do not need to be included on the

screening log because they have not met any of the exclusion criteria and are therefore eligible.

Patients that do not meet all of the inclusion criteria do not need to be recorded on the log.

What is the target population for Awake Prone?

Awake Prone wants to recruit a broad spectrum of patients with acute hypoxaemic respiratory failure.

Whilst we expect most patients will have a community acquired or hospital acquired pneumonia, we also expect to recruit patients with any other causes of respiratory failure, such as post-surgical respiratory failure and indirect causes of respiratory failure (e.g. extra-pulmonary sepsis/pancreatitis).

How does the study define acute hypoxaemic respiratory failure?

In Awake Prone, we define acute hypoxaemic respiratory failure as having required treatment with 40% oxygen or more for at least one hour.

It is important that the patient has both evidence of acute respiratory failure AND a clinical requirement for 40% oxygen or more. We would not expect to recruit the small group of acutely unwell patients who are routinely administered oxygen for other reasons (e.g. fitting; bleeding; anaphylaxis). The time requirement is used to exclude patients who require a higher amount of oxygen for a short period of time, such as those that become breathless following mobilisation.

Where a patient is receiving 40% oxygen or more, but there is evidence of hyperoxaemia (e.g. high SpO_2 or PaO_2), please consider weaning the oxygen in line with standard care to ensure there is a clinical requirement for 40% oxygen or more.

As stated in the protocol, there should be an ongoing requirement for 40% oxygen or more at the point of randomisation.

Once a patient meets the study eligibility criteria, how quickly do they need to be consented and randomised?

The study protocol does not mandate that patients are recruited within a specific period of time. The intervention of awake prone positioning is likely to be most effective when implemented early, so we would encourage sites to recruit as early as possible.

Is the participant eligible if they have pulmonary odema?

If a potential participant has acute hypoxaemic respiratory failure caused by pulmonary odema that is wholly explained by heart failure, then the individual is not eligible for Awake Prone.

Individuals with pulmonary odema may be eligible for Awake Prone if their acute hypoxaemic respiratory failure is caused by pulmonary odema not wholly attributable to

heart failure (e.g. combination of heart failure and another cause), or if their respiratory failure is attributable to both pulmonary odema and another cause (e.g. infection).

This should be a clinical assessment based on the available clinical information. Additional testing (e.g. point-of-care ultrasound) is not required to make this assessment.

What are contraindications to awake prone positioning?

The key issue to consider is whether there are patient or contextual factors that may make awake prone positioning unsafe. Patient contraindications to awake prone positioning include open abdominal wounds, unstable spinal fractures, and haemodynamic instability. Certain types of thoracic surgery, ENT surgery, or cardiac surgery may also be contraindications to awake prone positioning.

Does a potential participant need to be reviewed by a critical care clinician to determine suitability for tracheal intubation?

No.

The eligibility criteria requires that the patient would be eligible for tracheal intubation in the event of physiological deterioration. Given the study's target population is at high risk of deterioration, we would recommend that the clinical team consider treatment escalation planning as part of standard clinical care.

For Awake Prone, this process is not mandated and does not require referral to critical care. If the patient's own clinical team has not recommended against tracheal intubation, then the patient is potentially eligible.

Is a patient potentially eligible if they are receiving non-invasive respiratory support?

Yes. Patients receiving CPAP/HFNO/NIV are potentially eligible provided they meet criteria for acute hypoxaemic respiratory failure. We collect key settings for each type of non-invasive respiratory support at baseline (e.g. flow for HFNO).

The patient has been invasively ventilated during the current admission; are they potentially eligible?

The patient will only be potentially eligible for Awake Prone if they were intubated only for the purpose of facilitating a procedure or operation (e.g. imaging/ surgery/ endoscopy).

How do we determine patient willingness to attempt awake prone positioning?

Patients should be asked if they would be willing to attempt awake prone positioning if they were randomised to the awake prone positioning arm of the study. If they express a willingness to try, then they are potentially eligible. For patients who lack capacity, this willingness to attempt awake prone positioning should be sought from the patient before a consultee is approached to consent on the patient's behalf. Where a participant cannot

communicate this verbally, they may communicate this through non-verbal communication (e.g. thumbs up/ nodding head).

Are patients with hypercapnia eligible?

Yes.

Are patients with a DNACPR potentially eligible?

Yes. Where a patient has a DNACPR but would be eligible for tracheal intubation in the event of deterioration, they are potentially eligible.

Can patients with COVID-19 participate? Is a COVID-19 test required to determine eligibility?

If the primary cause of the patient's acute hypoxaemic respiratory failure is COVID-19 pneumonitis, then the patient is not eligible as we would expect awake prone positioning to form part of their routine clinical care.

If an individual is found to have COVID-19 by PCR test, but this is not deemed to be the cause of their acute hypoxaemic respiratory failure then the individual is potentially eligible.

A COVID-19 test is not required to determine eligibility.

What happens if the participant acquires COVID-19 during the hospital stay?

If COVID-19 is not the primary cause of the respiratory failure, then the patient is still eligible for the Awake Prone study – this will require clinical judgement.

If a participant develops COVID-19 following randomisation, then you will need to make a clinical judgement as to whether COVID-19 has become the primary cause of respiratory failure, such that there is now an absolute indication for awake prone positioning.

If it is determined that there is an absolute indication for awake prone positioning, please complete the End of Intervention Form in the Awake Prone database. You should continue to collect all data, including duration of awake prone positioning.

Are all causes of acute hypoxaemic respiratory failure potentially eligible?

Yes, subject to the notes on COVID-19 and pulmonary oedema detailed above.

Will there be a table to reference for conversion from litres of oxygen to 40% similar to other studies such as RECOVERY?

No, we have not created a table to convert lpm to % O_2. We are keen to be pragmatic and are aware that many sites may have developed their own conversions, such that we do not want to cause confusion. We assume most patients will receive O_2 via a device that delivers a specific O_2% (eg. humidified system / venturi).

Consent

Is consent taken multiple times for patients taking part in more than one CoReCCT trial?

Yes, consent is required for each CoReCCT trial.

Who can receive consent/consultee agreement?

Consent/consultee agreement can be received by anyone that is suitably trained and experienced and who has been delegated responsibility to undertake this role by the PI.

Will there be deferred consent?

No, although we will make use of consultee agreement for any participant unable to consent themselves. This can be a relative/friend or professional consultee. It is also necessary to ensure participant is willing to attempt awake prone position.