AWAKE PRONE

Frequently Asked Questions

Care delivery following randomisation

In which clinical settings can the intervention be delivered?

The study is designed to be delivered in any clinical setting in which it can be safely delivered in your hospital. During the set-up stage, we will confirm with you the target areas for recruitment and intervention delivery.

Following randomisation, what SpO_2 target should we aim for?

The SpO_2 for each patient should be set by the clinical team.

The study does not mandate a specific SpO_2 target.

Are there any treatments that are not permitted during the study?

No.

The study randomisation only influences patient position. All other treatments may be determined by the clinical team. These include non-invasive respiratory support (and settings), oxygen delivery device, antibiotics, and steroids. We do ask you to record key details about some treatments on the case report form.

Does the study require that any arterial blood gases are collected?

No.

We will, however, ask you to record the results of routinely collected arterial blood gases at key time points.

Does the study stipulate when patients should be intubated?

No.

The decision to intubate is a complex clinical decision that will be influenced by factors such as patient physiology, patient trajectory, and patient wishes. The decision to intubate is entirely at the discretion of the clinical team in collaboration with the patient.

What happens if a participant is transferred to a different hospital that is running Awake Prone, do they continue proning there?

If the receiving hospital is part of your NHS organisation and it is possible to continue the randomised allocation at the new hospital, then please continue, wherever possible, with the randomised allocation at the receiving hospital unless it has been discontinued for another reason (e.g. tracheal intubation).

Awake prone positioning

How quickly should awake prone positioning be started after randomisation?

As soon as possible.

What is the target duration of awake prone positioning per day?

The target duration is a minimum of 8 hours per day. This can be achieved through a single prolonged period or multiple shorter periods. Each period should be at least one hour.

How should the patient be positioned outside of time spent in the awake prone position?

Outside of times spent in the awake prone position, patients and their clinical teams can choose how they are positioned. This includes sitting out of bed, where appropriate.

What happens if the patient cannot tolerate awake prone positioning?

Patients should initially be positioned in the full prone position. If they find the position uncomfortable, we suggest the following steps:

1) Try and find out what the patient finds uncomfortable. This might be addressed through repositioning pillows, choosing a softer/ firmer pillow, or changing the tilt of the bed.

2) Reassure the patient that we know the position can be uncomfortable and try to encourage them to persevere if possible. If the patient's oxygen saturations have improved since lying in the prone position, it may be helpful and reassuring to tell them this.

3) Consider whether other interventions may be helpful to improve comfort, such as anti-emetics if feeling nauseous.

4) If these are unsuccessful, attempt the 3/4 prone position instead. Try and repeat the steps above to optimise comfort in the 3/4 prone position.

5) If the patient continues to find the prone position difficult to tolerate, then please try returning to a semi-recumbent position and trying again later.

What if the participant has spent no time proning today?

Record this on the proning log including a reason if possible.

Stopping the intervention

For someone randomised to awake prone positioning, what are the reasons for stopping the intervention?

The protocol lists seven reasons for stopping the intervention:

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 care setting where intervention could not be delivered, or

7) Participant transferred to another hospital.

What is meant by participant recovery?

Participants may recover before the end of the intervention period. We have not stipulated a definition of recovery but expect that this will be defined by the clinical team in collaboration with the participant. Potential markers of recovery include:

- Normalisation of respiratory rate
- Decreased shortness of breath
- Improvement in SpO_2 and reduced oxygen requirement

In general, an $SpO_2 \geq 94\%$ or more on $\leq 35\%$ supplemental oxygen would be a reasonable marker of recovery. It is expected that any clinical improvement is sustained after moving to a semi-recumbent position.

If the patient deteriorates after having been determined to have recovered, then further use of the awake prone position will be at the discretion of the clinical team.

What is meant by development of a contraindication to awake prone positioning?

This means the development of any clinical condition which would make use of awake prone positioning unsafe.

For example, if a patient requires surgery and returns from theatre with a large abdominal wound, then this would likely be deemed to be a contraindication.

What happens if following randomisation the participant's treatment escalation plan is reviewed, and they are determined to not be appropriate for tracheal intubation?

Where possible, the awake prone positioning intervention should be continued as per the randomisation allocation.

However, there may be cases where this is inappropriate, such as where there is a decision to transition from active treatment to palliation. In this context, we would classify this as a 'contraindication to awake prone positioning', allowing you to stop the intervention in line with the protocol.

Can the participant carry on proning after 5 days?

Yes.

Ongoing use of the awake prone position after day 5 (120 hours from randomisation) is at the discretion of the clinical team in collaboration with the participant. Where this is done, the case report form collects information on duration of awake prone positioning after day 5.