

INVASIVE MECHANICAL VENTILATION

*Patient receiving volume or pressure support from ventilator to support inspiration;
could be via ETT or tracheostomy*



EXTUBATION (NOT ONTO NIV)/ WEANING VIA TRACHEOSTOMY

*If patient is extubated, or weans via
tracheostomy, onto CPAP, High-Flow, or regular
oxygen therapy:*

- This constitutes unassisted breathing
- Note time IMV stops & alert clinical team
- Commence 48 hour monitoring period of unassisted breathing
- If 48 hours achieved successfully, this marks the primary outcome
- Clinical team to stop prescription of mucoactive (if patient in one of the 3 intervention groups)
- Record date and time of successful unassisted breathing on CRF i.e. date and time that marks the end of 48 hour period
- *NOTE – IT IS POSSIBLE TO ACHIEVE THE PRIMARY OUTCOME WITH A TRACHEOSTOMY IN SITU*
- *On rare occasions a patient may achieve the primary outcome with an ETT in situ if weaning has occurred before extubation*



EXTUBATION ONTO NIV

*If patient is extubated onto non-invasive
ventilation that continues to provide pressure or
volume support for inspiration:*

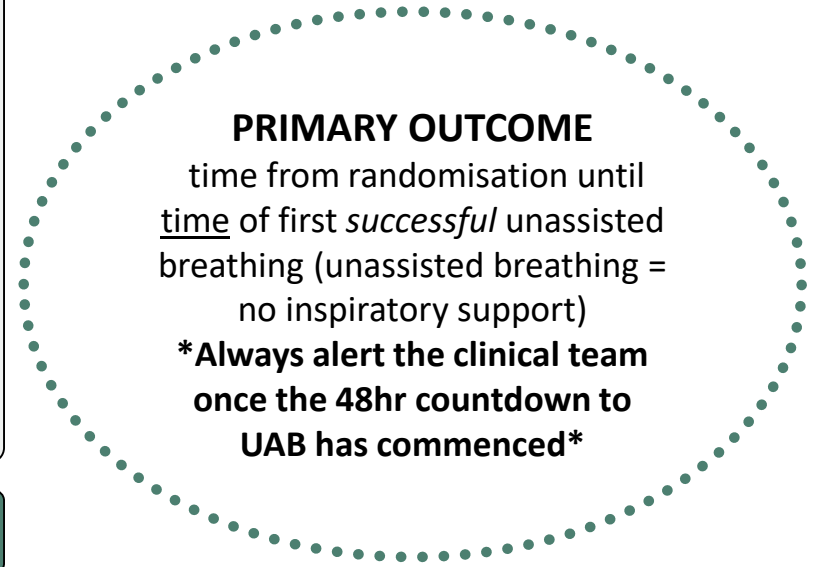
- This continues the period of mechanical ventilation
- Unassisted breathing commences when NIV is changed to CPAP, High-Flow, or regular oxygen therapy
- Note time NIV stops & alert clinical team
- Commence 48 hour monitoring period of unassisted breathing
- If 48 hours achieved successfully, this marks the primary outcome
- Clinical team to stop prescription of mucoactive (if patient in one of the 3 intervention groups)
- Record date and time of successful unassisted breathing on CRF i.e. date and time that marks the end of 48 hour period

See overleaf for example scenarios

PRIMARY OUTCOME
time from randomisation
until first *successful*
unassisted breathing
(unassisted breathing = no
inspiratory support)



**Any IMP administered after
the point of successful
UAB/primary outcome is
considered a protocol
deviation unless a clinical
decision to continue is made.
This decision must be clearly
documented in the notes.**



PRIMARY OUTCOME

time from randomisation until time of first successful unassisted breathing (unassisted breathing = no inspiratory support)

Always alert the clinical team once the 48hr countdown to UAB has commenced

★ REMEMBER ★

Any IMP administered after the point of successful UAB/primary outcome is considered a protocol deviation unless a clinical decision to continue is made. This decision must be clearly documented in the notes.

Example Patient Scenario 1

- Patient AB randomised 08/03/2024.
- Received tracheostomy and immediately commenced CPAP via trache mask 12/03/2024 at 11:00.
- ***Period of unassisted breathing commences – alert clinical team***
- Maintained on CPAP and regular oxygen for 48h.
- Achieved successful unassisted breathing/ primary outcome 14/03/2024 at 11:00.
- ***IMP prescription terminated at 11:00***
- Patient decannulated 26/03/2024 and maintained for 48 hours.
- Date of extubation 26/03/2024.

Example Patient Scenario 2

- Patient BC randomised 04/12/2023; no tracheostomy in situ.
- Extubated onto CPAP 15/12/2023 at 15:30.
- ***Period of unassisted breathing commences – alert clinical team***
- Maintained for 48h. Achieved successful unassisted breathing/ primary outcome 17/12/2023 at 15:30.
- ***IMP continued post-15:30 as per treating physician decision & documented in notes***
- Date of extubation 15/12/2024.

Example Patient Scenario 3

- Patient DE randomised 02/01/2024; no tracheostomy in situ.
- Extubated onto NIV 10/01/2024.
- Transition from NIV to high-flow 16/01/2024 at 17:00.
- ***Period of unassisted breathing commences – alert clinical team***
- Maintained on high-flow for 48h.
- Achieved successful unassisted breathing/ primary outcome 18/01/2024 at 17:00.
- ***IMP prescription terminated at 17:00***
- Date of extubation 16/01/2024.

Example Patient Scenario 4

- Patient EF randomised 04/03/2024.
- Weaned to CPAP with ETT in situ 10/04/2024 at 10:15.
- ***Period of unassisted breathing commences – alert clinical team***
- Maintained for 48h.
- Achieved successful unassisted breathing/ primary outcome 12/04/2024 at 10:15 with ETT in situ.
- ***IMP prescription terminated at 10:15***
- Extubated on same day and maintained for 48h.
- Date of extubation 12/04/2024.