

Attributes

Patient demographics

* Gender **dmg_sex**

Male (1)

Female (2)

* Ethnicity **dmg_ethnic**

Hispanic or Latino (1)

Not Hispanic or Latino (2)

Not reported (-1)

* Race (select all that apply)

American Indian or Alaskan Native **dmg_native**

Asian **dmg_asian**

Black or African American **dmg_afamer**

Native Hawaiian or other Pacific Islander **dmg_island**

White **dmg_white**

Not reported **dmg_norace**

Demographics complete

dmg_complete

Attributes

Death date

Death Date:

deathdt

Attributes

Contact completion

Contact information completed [ci_complete](#)

Contact information has been completed.

*

Contact information has not been completed.

- Click "Save and return" to go back to the dashboard.
- Use the project menu to go to the "LTO Data" study.
- Enroll the subject in the "LTO Data" study if not already done.
- Click the "Edit subject" button and fill out the contact data form.
- Click "Save and return" to save changes.
- Use the project menu to return to the current study.

Attributes

Study participation

ROSE [study_rose](#)

Enrollment date

[study_roseenrolldt](#)

Discontinuation date

[study_rosediscondt](#)

“Other” date

[study_roseothdt](#)

Attributes

Randomization

This form cannot be completed until after the screening form has been completed and the patient has been enrolled in the study.

Date and time of randomization:

* rand_dt * rand_tm

* What was the treatment assignment provided by the randomization system?

NMB (intervention) (1)

Usual care (control) (2)

* What was the randomziation id provided by the randomization system?

rand_randid

RAND complete

rand_complete

Attributes

sofa_bilih_d01 sofa_urineout_d01 sofa_anyvasoyn_d01 sofa_dopyn_d01 sofa_epinyn_d01 sofa_neosynyn_d01 sofa_vasopyn_d01
 SOFA sofa_platl_d01 sofa_creath_d01 sofa_mapld01 sofa_dobutyn_d01 sofa_dopdose_d01 sofa_epindose_d01 sofa_neosyndose_d01

Day	Date	Platelets (lowest) x 10 ³ /µL	Bilirubin (highest) mg/dL	Creatinine (highest) mg/dL	Total UOP ml/day	MAP (lowest) mmHg	Any vasopressors > 1 hour?	Dobutamine	Dopamine µg/kg/min	Epinephrine µg/kg/min	Norepinephrine µg/kg/min	Neosyneprine µg/kg/min	Vasopressin
1	* sofa_dt_d01	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
2	* sofa_dt_d02	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
3	* sofa_dt_d03	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
4	* sofa_dt_d04	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
5	* sofa_dt_d05	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
6	* sofa_dt_d06	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
7	* sofa_dt_d07	_____	_____	_____	_____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
14	* sofa_dt_d14	_____	_____	_____	* _____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
21	* sofa_dt_d21	_____	_____	_____	* _____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No
28	* sofa_dt_d28	_____	_____	_____	* _____	* _____	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes * _____ <input type="radio"/> No _____	* <input type="radio"/> Yes <input type="radio"/> No

SOFA randomization date _____
 SOFA discontinuation date _____
 SOFA death date _____
 SOFA complete [sofa_complete](#)
 SOFA version [sofa_version](#)

**replace the suffix with the correct day i.e. sofa_platl_d01 for day 2

Attributes

Patient status and study termination

Begin completing this form no later than day 28. Patients not yet home should be followed through day 90.

Was patient actually discontinued from the study before completion, with no further data collection? **stat_ptdiscontreally**

Yes (1)

No (2)

* What is the current patient status? **stat_status**

Home (1)

Dead prior to home (2)

Other (alive but not home) (888)

* Status date

stat_dt

Date of "home w/UAB" status

stat_dthomeuab

Date patient died

stat_dtdeath

Date of "other" status

stat_dtother

Discontinuation date

stat_dtdiscont

* Was the patient discharged alive from the study hospital before day 90? **st_hospdcyn**

Yes (1)

No (2)

* Date patient discharged

st_hospdcdt

* Was the patient permanently withdrawn from the trial before day 28 (study completion does not qualify as withdrawal)? **st_rosewdraw**

Yes (1)

No (2)

* Date of withdrawal

st_rosewdrawdt

* Reason for withdrawal

st_rosewdrawreas

STAT complete **stat_complete**

STAT version

stat_version

Attributes

Weaning Version 2.0

* Was the patient extubated between randomization and day 28? `st_extubyn`

Yes (1)

No (2)

* Date patient first extubated:

`st_extubdt`

* Was patient re-intubated before day 28 (do not include elective intubation for procedure/surgery)? `st_retubyn`

Yes (1)

No (2)

* Date of first re-intubation

`st_retubdt1`

Date of second re-intubation

`st_retubdt2`

STWEAN complete

`stwean_complete`

STWEAN version

_____ `st_wean_version`

Attributes

ICU history

Please record all study hospital ICU discharges and re-admissions between randomization and study day 28.

****st_dischargeyn_r1**

	Admission date	Discharged?	Discharge date	Re-admitted?	
Initial	<i>(On APACHE form)</i>	* <input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <u>st_dischargedt_r1</u>	* <input type="radio"/> Yes (1) <input type="radio"/> No (2)	st_readmityn_r1
Second	* <u>st_admitdt_r2</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r2</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r2
Third	* <u>st_readmityn_r3</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r3</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r3
Fourth	* <u>st_readmityn_r4</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r4</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r4
Fifth	* <u>st_readmityn_r5</u>	* <input type="radio"/> Yes <input type="radio"/> No	* <u>st_dischargedt_r5</u>	* <input type="radio"/> Yes <input type="radio"/> No	st_readmityn_r5

STICU
complete

****replace the suffix with appropriate iteration****

[sticu_complete](#)

Attributes

Ventilator history

* Was patient alive and on unassisted breathing on study days 27 and 28 (select 'yes' if the patient was discharged home on unassisted breathing prior to day 28)? `st_uabyn`

Yes (1)

No (2)

* Last date patient on assisted breathing

`st_assisteddt`

STVENT complete

`stvent_complete`

Attributes

Dialysis history

* Did the patient receive renal replacement therapy (RRT) between randomization and day 28? `st_dialyn`

Yes (1)

No (2)

* Date patient first received RRT

`st_dialfirstdt`

* Date patient last received RRT

`st_diallastdt`

STDIAL complete

`stdial_complete`

Attributes

SVT and barotrauma history

st_svtyn	Did this occur on study dates 0-2 (after randomization)
* Did the patient develop a supraventricular tachycardia (SVT), including atrial fibrillation, during the ICU stay? <input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_svt48hr
* Did the patient have a new pneumothorax between randomization and day 7? st_pneumothxyn * Was a chest tube required? st_chesttubeyn <input type="radio"/> Yes <input type="radio"/> No	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_pneumothx48hr
* Did the patient have a new pneumomediastinum between randomization and day 7? <input type="radio"/> Yes (1) <input type="radio"/> No st_pneumomedyn	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_pneumomed48hr

STSVT complete

stsvt_complete

Attributes

Rescue procedure history

Did the patient receive any of the following rescue procedures while on study (randomization through day 28)?

Did this occur on study dates 0-2 (after randomization)

* Recruitment maneuver st_recruityn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_recruit48hr
* Proning st_proneyn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_prone48hr
* Inhaled nitric oxide st_noxyn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_nox48hr
* Inhaled epoprostenol sodium st_esodiumyn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_esodium48hr
* Airway pressure release ventilation st_aprvyn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_aprv48hr
* High frequency ventilation st_hfvyn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_hfv48hr
* ECMO st_ecmoyn	<input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <input type="radio"/> Yes (1) <input type="radio"/> No (2) st_ecmo48hr

STRPROC complete

[strproc_complete](#)

Attributes

Patient re-consent

* Was written consent obtained from the patient during study hospitalization? `st_wconsentyn`

Yes (1)

No (2)

* If not, why? `st_wconsentreas`

Patient died (1)

Patient never regained decision-making capability (2)

Patient declined further participation in study (3)

Other (888)

* Specify other reason patient not re-consented:

`st_wconsentreasspec`

STCONSENT complete

`stconsent_complete`

Screening

Screening

* Did the patient meet the following inclusion criteria? incl_allcrit

- i. age \geq 18
- ii. PaO₂/FiO₂ < 150, with PEEP \geq 8 cmH₂O
or, if ABG not available
SpO₂/FiO₂ ratio equivalent to PaO₂/FiO₂ < 150 with PEEP \geq 8 cmH₂O and a confirmatory SpO₂/FiO₂ between 1–6 hours after the initial SpO₂/FiO₂ determination.
- iii. Bilateral opacities not fully explained by effusions, lobar/lung collapse, or nodules
- iv. Respirator failure not fully explained by cardiac failure or fluid overload

Yes (1)

No (2)

* Reasons for exclusion (select all that apply)

- Not excluded excl_notexcl
- Mechanical ventilation for > 120 hours excl_gt120hrvent
- More than 48 hours since meeting inclusion criteria excl_gt48hrcrit
- Continuous neuromuscular blockade at enrollment excl_nmb
- Known pregnancy excl_preg
- ECMO excl_ecmo
- Chronic respiratory failure in outpatient setting (PaCO₂ > 60 mmHg) excl_chronrespfl60
- Home mechanical ventilation except for sleep-disordered breathing excl_homevent
- Actual body weight exceeding 1 kg/cm of height excl_obese
- Severe chronic liver disease (Child-Pugh score 12-15) excl_chronliv
- Bone marrow transplant within last year excl_marrowtrans
- Expected duration of mechanical ventilation < 48 hours excl_lt48mechvent
- Decision to withhold life-sustaining treatment excl_dnr
- Moribund patient not expected to survive 24 hours; if CPR provided, assess for moribund status > 6 hours from CPR conclusion excl_moribund
- Diffuse alveolar hemorrhage from vasculitis excl_vasculitis
- Burns covering >70% total body surface excl_burns
- Unwillingness to use the ARDS Network 6ml/kg PBW ventilation protocol excl_noardsventprot
- Previous hypersensitivity or anaphylactic reaction to cisatracurium excl_cisatracurium
- Neuromuscular conditions that may potentiate neuromuscular blockade and/or impair spontaneous ventilation excl_neuromuscular
- Neurologic conditions undergoing treatment for intracranial hypertension excl_neurologic

Screening

- Enrollment in an interventional ARDS trial with direct impact on neuromuscular blockade and PEEP `excl_coenroll`
- At the time of randomization, a PaO₂/FiO₂ (if available) > 200 mmHg `excl_oobpao2fio2`
- MD refusal `excl_mdrefuse`
- Patient or surrogate refusal `excl_ptrefuse`
- Surrogate unavailable `excl_nosurrogate`
- Not excluded but not enrolled `excl_notenrolled`

* Specify reason not enrolled:

excl_notenrolledspec

* Enrollment status: `screening_status`

- In screening
- Failed screening
- Passed screening

Qualifying CXR

Date and time of qualifying CXR:

* scr_qualcxrdt * scr_qualcxrtm

* Number of quadrants with opacities

scr_quads

Current intubation

Date and time of current intubation:

* scr_intubdt * scr_intubtm

* Location of current intubation `scr_intubloc`

- EMS (pre-hospital) (1)
- ED (2)
- Ward (3)
- ICU (4)
- OR (5)
- Referring hospital (6)

Qualifying P/F or S/F ratio

* Which was used to determine if the patient was eligible? `scr_qualpfsf`

- P/F ratio (1)
- S/F ratio (2)

Date and time of qualifying P/F or S/F:

Screening

* scr_qualpfsfdt * scr_qualpfsftm

* Qualifying PaO2 scr_qualpao2

_____ mmHg

* Qualifying SpO2 scr_qualspo2

_____ %

* Qualifying FiO2 scr_qualfio2

_____ (decimal)

* PEEP at time of qualifying P/F or S/F scr_qualpeep

_____ cm H2O

* SpO2 closest to time of qualifying ABG scr_abgspo2

_____ %

Other

* Month of year that patient met screening criteria incl_critmt

- January (1)
- February (2)
- March (3)
- April (4)
- May (5)
- June (6)
- July (7)
- August (8)
- September (9)
- October (10)
- November (11)
- December (12)

* Location inclusion criteria met incl_critloc

- EMS (pre-hospital) (1)
- ED (2)
- Ward (3)
- ICU (4)
- OR (5)
- Referring hospital (6)

* Age scr_agescreen

*For screen failure patients

* Age scr_ageelig

*For eligible patients

* Age scr_age

**Combined variable, screened and eligible. Use this for analysis.

Screening

* Location of ICU admission `scr_icuadmloc`

- MICU (1)
- SICU (2)
- Cardiac SICU (3)
- CCU (4)
- Neuro ICU (5)
- Bum (6)
- Trauma (7)
- Cancer unit (8)
- MICU/SICU (9)
- Other (888)

* Specify other location of ICU admission:

`scr_icuadmlocspec`

SCR complete

`scr_complete`

* SCR version

`scr_version`

Lung injury category

Select one primary and 0–5 secondary causes for lung injury.

If both pneumonia and sepsis are causes for lung injury, indicate pneumonia as primary.

	Primary	Secondary	None	
* Trauma	(1) <input type="radio"/>	(2) <input type="radio"/>	(0) <input type="radio"/>	<code>lic_trauma</code>
* Sepsis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<code>lic_sepsis</code>
* Multiple transfusion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<code>lic_transf</code>
* Aspiration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<code>lic_aspir</code>
* Pneumonia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<code>lic_pneumo</code>
* Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<code>lic_other</code>

* Select only **one** primary cause for lung injury.

* You must select a primary cause for lung injury.

* Specify other lung injury category:

`lic_otherspec`

Screening

* For sepsis, specify site of infection: `lic_sepsite`

- Thorax (1)
- Abdominal (2)
- Skin or soft tissue (3)
- Bacterial meningitis (4)
- Urinary tract (5)
- Central line infection (6)
- Sinuses (7)
- Other (888)

* Specify other site of infection:

`lic_sepsitespec`

LIC complete

[lic_complete](#)

Consent

* Has informed consent been obtained for participation in the ROSE study? `cons_roseconsent`

- Yes (1)
- No (2)

* Did patient consent to the collection of samples for future genetic research in ARDS? `cons_futconsenta`

- Yes (1)
- No (2)

* Did patient consent to the collection of samples for future genetic research in for other conditions? `cons_futconsento`

- Yes (1)
- No (2)

CONS complete [cons_complete](#)

Baseline

Please go to the "Edit Subject" area and enter the randomization date before continuing.

APACHE demographics

* Date of hospital admission

apd_hadmdt

* Type of hospital admission **apd_admtype**

- Medical (1)
- Surgical (scheduled) (2)
- Surgical (unscheduled) (3)
- Trauma (4)
- Other (888)

* Specify other type of hospital admission:

apd_admtypespec

Date and time of ICU admission:

* apd_icudt * apd_icutm

* Patient admitted directly from **apd_admitfrom**

- OR (1)
- Recovery room (2)
- ER (3)
- Floor (4)
- Another special care unit (5)
- another hospital (6)
- Direct admit (7)
- Stepdown unit (8)

* Is patient immediately post-operative from elective surgery? **apd_surgel**

- Yes (1)
- No (2)

* Is this an ICU re-admission? **apd_readmit**

- Yes (1)
- No (2)

* Is this an ICU re-admission within 24 hours? **apd_readmit24**

- Yes (1)
- No (2)

* Lowest Glasgow Coma score in the 24 hours prior to randomization:

apd_gcs

* Did the patient have a pneumothorax at time of randomization? **apd_pneumothx**

- Yes (1)
- No (2)

Baseline

* Measured height cm (1) apd_heightunits
apd_height _____ in (2)

* Measured weight kg (1) apd_weightunits
apd_weight _____ lbs (2)

Predicted body weight apd_pbw

Baseline Glasgow Coma Score

Enter values for the worst Glasgow Coma Score for the 24 hours prior to randomization. If not score is available in the medical record, assess and calculate the score.

* At the time of the score, was the patient on a sedative or neuromuscular blocker? apd_gcsnmb
 Yes (1)
 No (2)
 Score not obtained (999)

* Eye opening score: apd_gcseye
 None (1) (1)
 To pain (2) (2)
 To voice (3) (3)
 Spontaneous (4) (4)
 Score not obtained (999)

* Motor response score: apd_gcsmotor
 Flaccid (1) (1)
 Abnormal extension (2) (2)
 Abnormal flexion (3) (3)
 Flexion withdrawal (4) (4)
 Localizes to pain (5) (5)
 Obeys commands (6) (6)
 Score not obtained (999)

* Verbal response score: apd_gcsverbal
 None, or generally unresponsive on ventilator (1) (1)
 Incomprehensible (2) (2)
 Inappropriate, or questionably oriented if on ventilator (3) (3)
 Confused (4) (4)
 Oriented, or appears oriented on ventilator (5) (5)
 Score not obtained (999)

APD complete

[apd_complete](#)

* APD version

apd_version

APACHE demographics (chronic health)

Baseline

* Is chronic health information available? `apd_chronhealthyn`

Yes (1)

No (2)

APDCHG complete

`apdchg_complete`

For each condition, indicate whether it was present at hospital admission (and **prior** to randomization):

(1) (2)

	Yes	No	
* AIDS (do not include HIV positive without AIDS criteria)	<input type="radio"/>	<input type="radio"/>	<code>apd_aids</code>
* Leukemia (AML, CML, ALL, multiple myeloma)	<input type="radio"/>	<input type="radio"/>	<code>apd_leuk</code>
* Non-Hodgkin's Lymphoma	<input type="radio"/>	<input type="radio"/>	<code>apd_lymph</code>
* A solid tumor with metastasis	<input type="radio"/>	<input type="radio"/>	<code>apd_tumor</code>
* Immune suppression within the past 6 months (radiation, chemotherapy, or ≥ 0.3 mg/kg/day prednisone or equivalent)	<input type="radio"/>	<input type="radio"/>	<code>apd_immune</code>
* Hepatic failure with coma or encephalopathy	<input type="radio"/>	<input type="radio"/>	<code>apd_hepa</code>
* Cirrhosis	<input type="radio"/>	<input type="radio"/>	<code>apd_cirr</code>
* Diabetes mellitus	<input type="radio"/>	<input type="radio"/>	<code>apd_diab</code>
* A history of hypertension	<input type="radio"/>	<input type="radio"/>	<code>apd_hyper</code>
* A prior myocardial infarction	<input type="radio"/>	<input type="radio"/>	<code>apd_myocard</code>
* Congestive heart failure	<input type="radio"/>	<input type="radio"/>	<code>apd_heart</code>
* Peripheral vascular disease	<input type="radio"/>	<input type="radio"/>	<code>apd_vascular</code>
* Has the patient had a prior stroke with sequelae?	<input type="radio"/>	<input type="radio"/>	<code>apd_stroke</code>
* Dementia	<input type="radio"/>	<input type="radio"/>	<code>apd_dementia</code>
* Chronic pulmonary disease	<input type="radio"/>	<input type="radio"/>	<code>apd_chrpulm</code>
* Arthritis	<input type="radio"/>	<input type="radio"/>	<code>apd_arthritis</code>
* Peptic ulcer disease	<input type="radio"/>	<input type="radio"/>	<code>apd_ulcer</code>
* Chronic dialysis or peritoneal dialysis?	<input type="radio"/>	<input type="radio"/>	<code>apd_chrondial</code>

APDCH complete

`apdch_complete`

APACHE physiology (vitals)

Use available values from the 24 hours preceding randomization.

Measure	Lowest	Higest	<code>app_tempu</code>
Temperature	* <code>app_templ</code>	* <code>app_temph</code>	* <input type="radio"/> °C (1) <input type="radio"/> °F (2)
Systolic BP	* _____ mmHg	* _____ mmHg	
Mean arterial pressure	* _____ mmHg	* _____ mmHg	
Heart rate	* _____ bpm	* _____ bpm	
P/F ratio	* <code>app_pfl</code>		

Baseline

Measure	Lowest	Higest
Respiratory rate	* <u>app_respl</u> _____ breaths/min * On ventilator? <u>app_ventl</u> <input type="radio"/> Yes (1) <input type="radio"/> No (2)	* <u>app_resph</u> _____ breaths/min * On ventilator? <u>app_venth</u> <input type="radio"/> Yes (1) <input type="radio"/> No (2)

APPV complete appv_complete

APACHE physiology (i/o)

The following are cumulative values for the 24 hours **preceding** randomization.

- * Total fluid intake _____ ml app_fluidin
- * Total fluid output _____ ml app_fluidout
- * Urine output _____ ml app_urineout

APPIO complete appio_complete

APACHE physiology (hematology)

Use available values from the 24 hours preceding randomization.

	Only one value available	Lowest	Highest
Hct	<u>app_hctsing</u> <input type="checkbox"/>	<u>app_hctl</u> _____ %	<u>app_hcth</u> %
WBC	<u>app_wbcsing</u> <input type="checkbox"/>	<u>app_wbcl</u> /mm ³	<u>app_wbch</u> /mm ³
Platelets		<u>app_platl</u> X 10 ³ /μL	

APPH complete apph_complete

APACHE physiology (chemistry)

Use available values from the 24 hours preceding randomization.

	Only one value available	Lowest	Highest
Serum sodium	<input type="checkbox"/> <u>app_sodiumsing</u>	<u>app_sodiuml</u> _____ mEq/L	<u>app_sodiumh</u> _____ mEq/L

Baseline

	Only one value available	Lowest	Highest
Serum potassium	<input type="checkbox"/> <u>app_potass</u> app_potassing	<u>app_potasl</u> mEq/L	<u>app_potash</u> mEq/L
Serum BUN			<u>app_bun</u> mg/dl
Serum creatinine	<input type="checkbox"/> <u>app_creats</u> app_creatsing	<u>app_creatl</u> mg/dl	<u>app_creath</u> mg/dl
Serum creatinine (24–48 hours prior to randomization)		<u>app_creatl48prerand</u> mg/dl	
Serum glucose	<input type="checkbox"/> <u>app_glucsing</u>	<u>app_gluccl</u> mg/dl	<u>app_gluch</u> mg/dl
Serum albumin	<input type="checkbox"/> <u>app_albumsing</u>	<u>app_albuml</u> g/dl	<u>app_albumh</u> g/dl
Serum bilirubin			<u>app_bilih</u> mg/dl
Serum bicarbonate		<u>app_bicarbl</u> mEq/L	

APPC complete appc_complete

APPC version appc_version

Ventilator parameters

Record closest values prior to randomization.

Record values closest to 0800.

* Ventilator mode vent_mode

- Volume assist/control (1)
- Pressure assist/control (2)
- Pressure support ventilation (3)
- Volume SIMV (4)
- Pressure SIMV (5)
- Pressure controlled inverse ratio ventilation (PC-IRV) (6)
- High frequency oscillation ventilation (HFOV) (7)
- Pressure regulated volume control (PRVC) / ACV with autoflow (8)
- Other (including dual and alternative modes) (888)
- Not on assisted ventilation (-1)

* Specify other ventilator mode:

vent_modespec

* Set tidal volume:

vent_tidal mL

Baseline

- * Set inspiratory pressure increment (above PEEP): _____ cm H2O vent_insppres
- * Set rate: _____ breaths/min vent_rate
- * Total rate: _____ breaths/min vent_ratetotal
- * Set peak flow: _____ L/min vent_peakflow
- * Total minute ventilation: _____ L/min vent_minvent
- * Set PEEP: _____ cm H2O vent_peep
- * Peak inspiratory pressure: _____ cm H2O vent_pip
- * Plateau pressure: _____ cm H2O vent_pplat
- * Mean airway pressure: _____ cm H2O vent_meanair
- * FiO2: _____ (decimal) vent_fio2
- * SpO2: _____ % vent_spo2
- VENT complete vent_complete

ABG

Record closest pre-randomization ABG, only if within 24 hours prior to randomization.

If ABG available today, record closest to 0800.

- * Was an ABG available during this time? abg_yn
 Yes (1)
 No (2)
- * FiO2 _____ abg_fio2 (decimal)
- * PaO2 _____ abg_pao2 mmHg
- * PaCO2 _____ abg_paco2 mmHg
- * Arterial pH _____ abg_ph
- * SpO2 closest to time of ABG _____ abg_spo2 %
- ABG complete abg_complete

Ventilator baseline titration

Fill out the following information **after** titration to PEEP, if any was required to reach target PEEP/FiO2 combination.

- * Was titration of PEEP to the target PEEP/FiO2 combination required? vent_titration
 Yes (1)
 No (2)

Baseline

- * Set tidal volume vent_tidalpost ml
- * PEEP vent_peeppost cm H2O
- * Plateau pressure: vent_pplatpost cm H2O
- VENTTIT complete venttit_complete

Medications

Was the patient receiving any of the following medications in the 24 hours prior to randomization?

Was the patient receiving any of the following medications on this study day?

* Intravenous sedatives: meds_sed

- Yes (1)
- No (2)

* Sedatives given in this calendar day (select all that apply):

- Any benzodiazepine meds_benzo
- Ketamine meds_keta
- Propofol meds_propo
- Dexmedetomidine meds_dexmed
- MENDS II study drug meds_mendsii

* Intravenous opioids: meds_opioid

- Yes (1)
- No (2)

* Intravenous or enteral corticosteroids (≥ 20 mg methylprednisolone equivalents): meds_corticoster

- Yes (1)
- No (2)

MEDES complete

meds_complete

MEDES version

meds_version

Baseline sedation

Sedation level closest and prior to randomization (complete appropriate score for your site):

* Sedation scale: blsed_scale

- RASS (1)
- RIKER (2)
- RAMSAY (3)
- Not done* (-1)

* RASS score blsed_rass

Baseline

* RIKER score blsed_riker

* RAMSAY score blsed_ramsay

BLSED complete blsed_complete

Baseline mobility assessment

Is the patient missing any part of:

(1)	Yes	No	Not assessed	
* Right arm	<input type="radio"/>	<input type="radio"/>	(2) <input type="radio"/>	(999) blmob_rtarmmiss
* Left arm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_ltarmmiss
* Right leg	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_rtlegmiss
* Left leg	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_ltlegmiss

Prior to this illness, could the patient move:

	Yes	No	Not assessed	
* Right arm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_rtarmmove
* Left arm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_ltarmmove
* Right leg	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_rtlegmove
* Left leg	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	blmob_ltlegmove

BLMOB complete

blmob_complete

Baseline vasopressors

* Has the patient had any vasopressors lasting more than one hour in the 24 hours prior to randomization? blvaso_vasol24

Yes (1)

No (2)

* Record highest infusion for any vasopressor that was administered for at least one hour.

blvaso_dobutyn

Dobutamine

blvaso_dopyn

Dopamine

* _____ $\mu\text{g/kg/min}$ blvaso_dopdose

blvaso_epinyn

Epinephrine

* _____ $\mu\text{g/kg/min}$ blvaso_epindose

blvaso_norepinyn

Norepinephrine

* _____ $\mu\text{g/kg/min}$ blvaso_norepindose

blvaso_neosynyn

Neosynephrine

* _____ $\mu\text{g/kg/min}$ blvaso_neosyndose

blvaso_vasopyn

Vasopressin

BLVASO complete blvaso_complete

Intake and output

Record totals for the day of randomization.

Record totals for this 24-hour period.

Baseline

- * Total fluid intake _____ ml io_fluidin
- * Total fluid output _____ ml io_fluidout
- * Urine output _____ ml io_urineout
- IO complete io_complete

Sample collection

- * Was a sample collected at **this time period**? samp_yn

- Yes (1)
- No (2)

Actual date and time blood drawn for sample collection:

* samp_dt * samp_tm

* Accession number:

samp_accno

* Specify why sample was not collected:

samp_spec

SAMP complete

samp_complete

* SAMP version

samp_version

Alcohol history

- * Was the alcohol history collected? alhx_yn

- Yes (1)
- No (2)

- * How often do you have a drink containing alcohol? alhx_freq

- Never (0)
- Monthly or less (1)
- 2-3 times a month (2)
- 2-3 times a week (3)
- 4 or more times a week (4)
- Not answered* (777)

- * How many drinks containing alcohol do you have on a typical day when you are drinking? alhx_num

- 1 or 2 (1)
- 3 or 4 (3)
- 5 or 6 (5)
- 7, 8 or 9 (7)
- 10 or more (10)
- Not answered* (777)

Baseline

* How often do you have 6 or more drinks on one occasion? `alhx_freq6`

- Never (0)
- Less than monthly (1)
- Monthly (2)
- Weekly (3)
- Daily or almost daily (4)
- Not answered* (777)

ALHX complete

`alhx_complete`

Smoking history

* Was patient ever a smoker (i.e. more than 100 cigarettes in lifetime)? `smhx_smoker`

- Yes (1)
- No (2)

* Estimate the number of pack years:

(Pack years = number of packs per day × number of years)

`smhx_packyr`

* Is the patient still a smoker? `smhx_curr`

- Yes (1)
- No (2)

* When did the patient quit?

`smhx_quitdt`

SMHX complete

`smhx_complete`

Basic assessment of prior functioning [q]

Recent living status and hospitalization

* Before the current hospitalization (that is, about one month ago), where did the patient reside? `pfunc_reside`

- Home independently (1)
- Home with help (2)
- Home with professional help (3)
- Intermediate care or rehab facility (4)
- Skilled nursing facility (5)
- Another acute care hospital (6)
- Homeless or living in a temporary shelter (7)
- Adult Family Home or other non-medical institutional setting (8)
- Other (888)
- Not answered* (777)

* Specify other prior place of residence:

`pfunc_residespec`

Baseline

* During the month before this current hospitalization, about how many days was the patient in the hospital?

pfunc_hospdays

Not answered pfunc_hospdaysna

EQ-5D-5L

* Who was the EQ-5D-5L information obtained from? pfunc_source

- Co-resident spouse / partner (1)
- Non-co-resident spouse / partner (2)
- Co-resident child or parent (3)
- Non-co-resident child or parent (4)
- Co-resident other (5)
- Non-co-resident other (6)
- Not answered* (777)

* What language was the EQ-5D-5L conducted in? pfunc_language

- English (1)
- Spanish (2)
- Other language with translator (888)
- Not answered* (777)

* Please specify language

pfunc_languagespec

* Mobility pfunc_mobility

- I have no problems walking (1)
- I have slight problems walking (2)
- I have moderate problems walking (3)
- I am severe problems walking (4)
- I am unable to walk (5)
- Not answered* (777)

* Self-care pfunc_selfcare

- I have no problems washing or dressing myself (1)
- I have slight problems washing or dressing myself (2)
- I have moderate problems washing or dressing myself (3)
- I am severe problems washing or dressing myself (4)
- I am unable to wash or dress myself (5)
- Not answered* (777)

* Usual activities pfunc_usualact

- I have no problems doing my usual activities (1)
- I have slight problems doing my usual activities (2)
- I have moderate problems doing my usual activities (3)
- I am severe problems doing my usual activities (4)
- I am unable to do my usual activities (5)
- Not answered* (777)

Baseline

* Pain / discomfort pfunc_pain

- I have no pain or discomfort (1)
- I have slight pain or discomfort (2)
- I have moderate pain or discomfort (3)
- I have severe pain or discomfort (4)
- I have extreme pain or discomfort (5)
- Not answered (777)

* Anxiety / depression pfunc_anxdep

- I am not anxious or depressed (1)
- I am slightly anxious or depressed (2)
- I am moderately anxious or depressed (3)
- I am severely anxious or depressed (4)
- I am extremely anxious or depressed (5)
- Not answered (777)

Other ADLs and IADLs

Before the current illness, did the patient have any difficulties with the following tasks due to a health or memory problem:

* Eating, such as cutting up their food? pfunc_eating

- Yes (1)
- No (2)
- Don't do (6)
- Can't do (7)
- Don't know (8)
- Not answered (777)

* Getting in or out of bed? pfunc_bed

- Yes (1)
- No (2)
- Don't do (6)
- Can't do (7)
- Don't know (8)
- Not answered (777)

* Using the toilet, including getting up and down? pfunc_toilet

- Yes (1)
- No (2)
- Don't do (6)
- Can't do (7)
- Don't know (8)
- Not answered (777)

Baseline

* Preparing a hot meal? pfunc_cooking

- Yes (1)
- No (2)
- Don't do* (6)
- Can't do* (7)
- Don't know* (8)
- Not answered* (777)

* Shopping for groceries? pfunc_shopping

- Yes (1)
- No (2)
- Don't do* (6)
- Can't do* (7)
- Don't know* (8)
- Not answered* (777)

* Making phone calls? pfunc_telephoning

- Yes (1)
- No (2)
- Don't do* (6)
- Can't do* (7)
- Don't know* (8)
- Not answered* (777)

* Taking medications? pfunc_medication

- Yes (1)
- No (2)
- Don't do* (6)
- Can't do* (7)
- Don't know* (8)
- Not answered* (777)

* Managing their money, such as paying their bills and keeping track of expenses? pfunc_money

- Yes (1)
- No (2)
- Don't do* (6)
- Can't do* (7)
- Don't know* (8)
- Not answered* (777)

PFUNC complete

pfunc_complete

On Study Intervals

Please go to the "Edit Subject" area and enter the randomization date before continuing.

Ventilator parameters (Days 1-4, 7)

Record closest values prior to randomization.

Record values closest to 0800.

* Ventilator mode **vent_mode**

- Volume assist/control (1)
- Pressure assist/control (2)
- Pressure support ventilation (3)
- Volume SIMV (4)
- Pressure SIMV (5)
- Pressure controlled inverse ratio ventilation (PC-IRV) (6)
- High frequency oscillation ventilation (HFOV) (7)
- Pressure regulated volume control (PRVC) / ACV with autoflow (8)
- Other (including dual and alternative modes) (888)
- Not on assisted ventilation* (-1)

* Specify other ventilator mode:

vent_modespec

- * Set tidal volume: _____ mL **vent_tidal**
- * Set inspiratory pressure increment (above PEEP): _____ cm H2O **vent_insppres**
- * Set rate: _____ breaths/min **vent_rate**
- * Total rate: _____ breaths/min **vent_ratetotal**
- * Set peak flow: _____ L/min **vent_peakflow**
- * Total minute ventilation: _____ L/min **vent_minvent**
- * Set PEEP: _____ cm H2O **vent_peep**
- * Peak inspiratory pressure: _____ cm H2O **vent_pip**
- * Plateau pressure: _____ cm H2O **vent_pplat**
- * Mean airway pressure: _____ cm H2O **vent_meanair**
- * FiO2: _____ (decimal) **vent_fio2**
- * SpO2: _____ % **vent_spo2**
- VENT complete **vent_complete**

ABG (Day 1-4, 7)

On Study Intervals

Record closest pre-randomization ABG, only if within 24 hours prior to randomization.

If ABG available today, record closest to 0800.

- * Was an ABG available during this time? **abg_yn**
 - Yes (1)
 - No (2)

- * FiO2 abg_fio2 (decimal)

- * PaO2 abg_pao2 mmHg

- * PaCO2 abg_paco2 mmHg

- * Arterial pH abg_ph

- * SpO2 closest to time of ABG abg_spo2 %

- ABG complete **abg_complete**

Medications (Days 1-4, 7)

Version 2.0

Was the patient receiving any of the following medications in the 24 hours prior to randomization?

Was the patient receiving any of the following medications on this study day?

- * Intravenous sedatives: **meds_sed**
 - Yes (1)
 - No (2)

- * Sedatives given in this calendar day (select all that apply):
 - Any benzodiazepine **meds_benzo**

 - Ketamine **meds_keta**

 - Propofol **meds_propo**

 - Dexmedetomidine **meds_dexmed**

 - MENDS II study drug **meds_mendsii**

- * Intravenous opioids: **meds_opioid**
 - Yes (1)
 - No (2)

- * Intravenous or enteral corticosteroids (≥ 20 mg methylprednisolone equivalents): **meds_corticoster**
 - Yes (1)
 - No (2)

- MEDS complete **meds_complete**

- MEDS version meds_version

On Study Intervals

Intake and output (Days 1-7)

Record totals for the day of randomization.

Record totals for this 24-hour period.

- * Total fluid intake _____ ml io_fluidin
- * Total fluid output _____ ml io_fluidout
- * Urine output _____ ml io_urineout
- IO complete io_complete

Fluid protocol check (Days 1-7)

- * Were maintenance fluids running between 0001 and 0800 this calendar day? fpc_maintfluyn
 - Yes (1)
 - No (2)
- * Was patient in renal failure or receiving renal replacement therapy on this calendar day? fpc_renalyn
 - Yes
 - No
- * Was CVP measured this calendar day? fpc_cvpyn
 - Yes
 - No
- * What was the CVP closest to 0800?
fpc_cvp _____
- * In the 12 hours prior to the CVP value, did patient receive vasopressors? fpc_vaso12prior
 - Yes (1)
 - No (2)
- * In the 12 hours prior to the CVP value, was a fluid bolus (>15 ml/kg PBW) given? fpc_bolus12
 - Yes (1)
 - No (2)
- * In the 12 hours prior to the CVP value, did the MAP fall below 60 mmHg? fpc_map60
 - Yes (1)
 - No (2)
- * In the 4 hours after the CVP value above, was lasix given? fpc_lasix4post
 - Yes (1)
 - No (2)
- * Was the average UOP In the 4 hours prior to the CVP value < 0.5 ml/kg/hr? fpc_avuop4
 - Yes (1)
 - No (2)
- FPC complete
 fpc_complete

Sample collection (Days 1-2)

Version 2.0

On Study Intervals

* Was a sample collected at **this time period**? **samp_yn**

- Yes (1)
- No (2)

Actual date and time blood drawn for sample collection:

* samp_dt * samp_tm

* Accession number:

samp_accno

* Specify why sample was not collected:

samp_spec

SAMP complete

samp_complete

* SAMP version

samp_version

Labs (Days 1-4, 7)

Record lab values closest to 0800, if available.

Serum potassium _____ mEq/L **labs_potas**

Serum glucose _____ mg/dL **labs_gluc**

Serum bicarbonate _____ mEq/L **labs_bicarb**

LABS complete **labs_complete**

Sedation (Days 1-7)

Version 2.0

Select and record the score for sedation level closest to 8am from the list below. If the patient is on a Spontaneous Awakening Trial (SAT) at 8am, give the sedation level immediately prior to SAT.

* Sedation scale: **sed_scale**

- RASS (1)
- RIKER (2)
- RAMSAY (3)
- Not done* (-1)

* RASS score sed_rass

* RIKER score sed_riker

* RAMSAY score sed_ramsay

* Was sedation administered in the 6 hour interval before the sedation score above? **sed_prev6hrs** (ONLY DAY 1)

- Yes (1)
- No (2)

* Reason(s) for sedation in the 6 hours prior to the sedation score (select all that apply):

On Study Intervals

Ventilator dyssynchrony `sed_ventdyss`

Severe or worsening respiratory failure `sed_respfail`

Prone `sed_prone`

Drug withdrawal `sed_drug`

Agitation `sed_agit`

Delirium `sed_delirium`

Hypertension `sed_hypert`

Tachycardia `sed_tachy`

On NMB `sed_nmb`

Other `sed_other`

* Specify other reason for sedation:

sed_otherspec

Transport / procedures `sed_transproc`

After chart review and/or discussion with ICU team, no apparent reason identified `sed_unknown`

* Was a sedation interruption performed this study day? `sed_interrupt`

Yes (1)

No (2)

Not applicable (-1)

SED complete

`sed_complete`

SED version

SED version (2)

sed_version2

Activity (Days 1-7, 14, 21, 28)

* Has the patient moved arms or legs today (including squeezing hands or wiggling toes)? `act_ptmovedd3`

(ONLY ON DAY 3)

Yes (1)

No (2)

* Source of information `act_ptmovedd3src`

Medical record (1)

Bedside clinician (2)

Coördinator assessment (3)

On Study Intervals

* Highest level of physical activity achieved this study day `act_physactiv`

- None (0)
- Sitting in / exercising in bed (1)
- Passively moved to chair (2)
- Sitting over edge of bed (3)
- Standing (4)
- Transfer bed to chair (5)
- Marching on spot (at bedside) (6)
- Walk with assist of 2 or more (7)
- Walk with assist of 1 person (8)
- Walk independently with gait aid (9)
- Walk without gait aid (10)

* Source of information `act_physactivsrc`

- Medical record (1)
- Bedside clinician (2)

ACT complete `act_complete`

On Study Intervals

On Ventilator Days 5-6

* Was the patient on assisted breathing during this calendar day? fpc_ventyn

Yes (1)

No (2)

FPC on vent complete fpcvent_complete

On Study Intervals

MMT [g]

* Are there safety barriers to strength testing (such as unstable shock, profound hypoxemia, etc.)? mmt_unsafe

- Yes (1)
- No (2)
- Unable to assess* (999)

* Was the patient able to respond appropriately to all five attention screening commands?

- Yes (1)
- No (2)
- Unable to assess* (999)

MMTG complete

mmtg_complete

On Study Intervals

Indicate score (0-5) for each side of each muscle group.

Group assessed:	Right	Left
Shoulder abduction	* <u>mmt_sar</u> <input type="checkbox"/> unable to assess mmt_nosar	* <u>mmt_sal</u> <input type="checkbox"/> unable to assess mmt_nosal
Elbow flexion	* <u>mmt_evr</u> <input type="checkbox"/> unable to assess mmt_noefr	* <u>mmt_evl</u> <input type="checkbox"/> unable to assess mmt_noefl
Wrist extension	* <u>mmt_wer</u> <input type="checkbox"/> unable to assess mmt_nower	* <u>mmt_wel</u> <input type="checkbox"/> unable to assess mmt_nowel
Hip flexion	* <u>mmt_hfr</u> <input type="checkbox"/> unable to assess mmt_nohfr	* <u>mmt_hfl</u> <input type="checkbox"/> unable to assess mmt_nohfl
Knee extension	* <u>mmt_ker</u> <input type="checkbox"/> unable to assess mmt_noker	* <u>mmt_kel</u> <input type="checkbox"/> unable to assess mmt_nokel
Foot dorsiflexion	* <u>mmt_fdr</u> <input type="checkbox"/> unable to assess mmt_nofdr	* <u>mmt_fdl</u> <input type="checkbox"/> unable to assess mmt_nofdl

* Was the MMT assessment fully completed? mmt_comp

Yes (1)

No (2)

* Please specify reason MMT was not fully completed:

Patient unavailable mmt_ncptunavail

Study staff unavailable mmt_ncnostaff

Patient refused mmt_ncptref

Family refused mmt_ncfamref

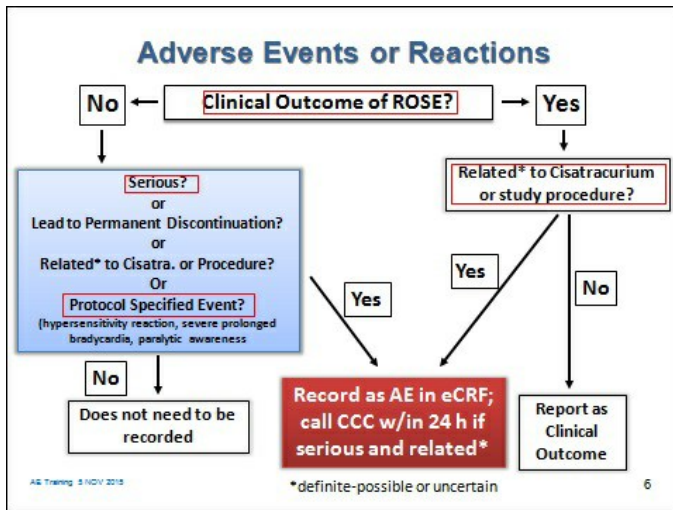
Patient's clinicians refused mmt_ncclinref

Language barrier mmt_nclang

Missing limb mmt_ncmisslimb

Adverse Event

Adverse event



Date and time of adverse event:

* ae_dt _____ * ae_tm _____

* Defined MedDRA term ae_meddra

- Other (-1)
- Paralysis recall (-100)
- Severe prolonged bradycardia (-101)
- Hypersensitivity reaction (20000214)

* COSTART term

ae_userterm _____ [[lookup tool](#)]

MedDRA code ae_meddracode _____

* Description of adverse event

ae_desc _____

* Was the adverse event serious? ae_serious

- Yes (1)
- No (2)

* Was the adverse event related to the cisatracurium bolus or infusion? ae_causerose

- Definitely related (1)
- Probably or possibly related (2)
- Probably not related (3)
- Definitely not related (4)
- Uncertain relationship (5)

Adverse Event

* Was the adverse event unexpected (not listed in the cisatracurium package insert)? **ae_unexpectedcisatr**

- Yes (1)
- No (2)

* Was the adverse event related to other study procedures? **ae_causestudy**

- Definitely related (1)
- Probably or possibly related (2)
- Probably not related (3)
- Definitely not related (4)
- Uncertain relationship (5)

* Was the cisatracurium infusion stopped because of the adverse event? **ae_wdrawrose**

- Yes (1)
- No (2)

* What was the status of the adverse event at the time of the initial AE report? **ae_status**

- Recovered (1)
- AE present, no treatment (2)
- AE present, being treated (3)
- Residual effect / no treatment (4)
- Residual effect / being treated (5)
- Deceased as a result of the AE (6)

* What was the final outcome of the adverse event? **ae_outcome**

- Recovered (1)
- AE present, no treatment (2)
- AE present, being treated (3)
- Residual effect / no treatment (4)
- Residual effect / being treated (5)
- Deceased as a result of the AE (6)

* Date of recovery

ae_recdt _____

AE complete **ae_complete**

* AE version

ae_version _____

Study Initiation and Drug Dosage

Study initiation and drug dosing Version 5.0

What was the treatment assignment provided by the randomization system? `sidd_treatment`

- NMB (intervention) (1)
- Usual care (control) (2)

* Did the patient receive any neuromuscular blockers between the time of meeting all inclusion criteria and the time of randomization? `sidd_nmbprerand`

- Yes (1)
- No (2)

* Was the patient at target PEEP/FiO2 at time of randomization? `sidd_atpeep`

- Yes (1)
- No (2)

* Was PEEP titration attempted? `sidd_tityn`

- Yes (1)
- No (2)

Date and time of first protocol specified PEEP and FiO2 titration:

* `sidd_titdt` * `sidd_tittm`

* Was the patient on any vasopressors at the time of randomization? `sidd_onvaso`

- Yes (1)
- No (2)

* Was the patient at target sedation level at time of randomization? (RASS: [-4,-5]; RIKER: [1,2]; `sidd_atsed` RAMSAY: [5,6])

- Yes (1)
- No (2)

Date and time of initiation of sedation to target sedation level:

* `sidd_sedstdt` * `sidd_sedsttm`

Date and time of target sedation level achieved:

* `sidd_sedachdt` * `sidd_sedachtm`

* Was a fluid bolus given in the 6-hour interval following randomization? `sidd_bolus`

- Yes (1)
- No (2)

Times fluid boluses administered:

`sidd_bolustm1` `sidd_bolustm2`

* 1: _____ 2: _____ 3: `sidd_bolustm3`

* Were vasopressors started or increased in the 6-hour interval following randomization? `sidd_vasop`

- Yes (1)
- No (2)

Times of vasopressor adjustments:

* 1: _____ 2: _____ 3: `sidd_vasoptm3`
`sidd_vasoptm1` `sidd_vasoptm2`

Study Initiation and Drug Dosage

* Total fluid intake in the 6 hour interval following randomization:

sidd_fluidin _____ ml

* Total fluid output in the 6 hour interval following randomization:

sidd_fluidout _____ ml

* Was a cisatracurium bolus given? sidd_loadyn

- Yes (1)
 No (2)

Date and time of cisatracurium loading dose:

* sidd_loaddt _____ * sidd_loadtm _____

* Loading dose

_____ mg sidd_loadamt

* Was a cisatracurium infusion started? sidd_infuseyn

- Yes (1)
 No (2)

Date and time of initiation of cisatracurium infusion:

* sidd_infusedt _____ * sidd_infusetm _____

* Hourly infusion rate

_____ mg/hour sidd_infuserate

* Was infusion temporarily stopped during the 48-hour study infusion period? sidd_held

- Yes (1)
 No (2)

Duration and reason of first hold:

sidd_heldmin1

* Duration: _____ mins * Reason: sidd_heldreas1 _____

Duration and reason of second hold (if applicable):

sidd_heldmin2

Duration: _____ mins Reason: sidd_heldreas2 _____

Duration and reason of third hold (if applicable):

sidd_heldmin3

Duration: _____ mins Reason: sidd_heldreas3 _____

Date and time study cisatracurium infusion completely or permanently stopped:

* sidd_stopdt _____ * sidd_stoptm _____

* Was the cisatracurium infusion permanently stopped prior to completion of the first 48 hours? sidd_stopearly

- Yes (1)
 No (2)

Study Initiation and Drug Dosage

* Why was the cisatracurium infusion stopped before the first 48 hours? sidd_stopearlyreason

- Infusion was stopped because the patient met cisatracurium stopping allowance (1) criteria (FiO₂ ≤0.40 and PEEP ≤8 cm for at least 12 hours)
- Death (2)
- Adverse event (report using adverse event form) (3)
- Withdrawn from study (4)
- Infusion stopped early as cisatracurium total dose was complete in less than 48 (5) hours (not a protocol deviation)
- Unintentional early stop (medication error, protocol deviation) (6)
- Other (888)

* Please specify why cisatracurium infusion was stopped early:

sidd_stopearlyreasonspec

For intervention patients:

The first 48 hour period refers to the initial 48 hour study infusion period.

The second 48 hour period refers to the subsequent 48 hours following the initial infusion period.

For control patients:

The first 48 hour period refers to the 48 hours following randomization.

The second 48 hour period refers to the subsequent 48 hours following randomization.

* Were additional cisatracurium boluses administered during the 48-hour study infusion period? sidd_addtlcisbolyn

- Yes (1)
- No (2)

* Number of additional cisatracurium boluses:

sidd_addtlcisbolnum

* Total amount of cisatracurium administered in additional boluses:

_____ mg sidd_addtlcisbolmg

* Was the cisatracurium infusion rate increased above 37.5 mg/hr at any point during the 48-hour study infusion period? sidd_infchgyn

- Yes (1)
- No (2)

* Rate: sidd_infchgrate1 _____ mg/hr * Duration: _____ mins sidd_infchgdur1

Rate: sidd_infchgrate2 _____ mg/hr Duration: _____ mins sidd_infchgdur2

Rate: sidd_infchgrate3 _____ mg/hr Duration: _____ mins sidd_infchgdur3

* Were any other neuromuscular blockers given in the first 48-hour study period? sidd_nmb1st48

- Yes (1)
- No (2)

* Record total amount of neuromuscular blockers given in this 48-hour period:

sidd_nmb1st48cisyn

Cisatracurium * _____ mg sidd_nmb1st48cis

sidd_nmb1st48atryn

Atracurium * _____ mg sidd_nmb1st48atr

sidd_nmb1st48rocyn

Rocuronium * _____ mg sidd_nmb1st48roc

Study Initiation and Drug Dosage

sidd_nmb1st48panyn

Pancuronium * _____ mg sidd_nmb1st48pan

sidd_nmb1st48vecyn

Vecuronium * _____ mg sidd_nmb1st48vec

sidd_nmb1st48othyn sidd_nmb1st48oth

Other * _____ mg * (specify: sidd_nmb1st48othspec)

* Were any neuromuscular blockers given in the second 48-hour study period? sidd_nmb2nd48

Yes (1)

No (2)

* Record total amount of neuromuscular blockers given in this 48-hour period:

sidd_nmb2nd48cisyn

Cisatracurium * _____ mg sidd_nmb2nd48cis

sidd_nmb2nd48atryn

Atracurium * _____ mg sidd_nmb2nd48atr

sidd_nmb2nd48rocyn

Rocuronium * _____ mg sidd_nmb2nd48roc

sidd_nmb2nd48panyn

Pancuronium * _____ mg sidd_nmb2nd48pan

sidd_nmb2nd48vecyn

Vecuronium * _____ mg sidd_nmb2nd48vec

sidd_nmb2nd48othyn sidd_nmb2nd48oth

Other * _____ mg * (specify: sidd_nmb2nd48othspec)

* Were any neuromuscular blockers given at any time after the 2nd 48-hour study period? sidd_nmbafter2nd48

Yes (1)

No (2)

SIDD complete sidd_complete

* SIDD version

sidd_version

Modified Brice

Modified Brice questionnaire

* Was this questionnaire able to be completed? brice_yn

- Yes (1)
- No (2)

* If not completed, why not? brice_notcomp

- Never passed attention screen (1)
- Never extubated (2)
- Never able to speak (3)
- Does not speak English (4)
- Discharged before coordinator able to complete (5)
- Patient refused (6)
- Other (8)

* Please specify reason Brice not completed

brice_notcompspec

BRICEG complete

briceg_complete

Collect one time during hospitalization.

* Date of assessment

brice_dt

* What was the last thing you remember before going to sleep? (Choose one) brice_1stmem

- Being with family (1)
- Feeling mask on face (2)
- Burning or stinging in the IV line (3)
- Hearing voices (4)
- Other (5)

* Specify the last thing you remember before going to sleep:

brice_1stmemspec

* What is the first thing you remember after waking up? (Choose one) brice_frstmem

- Hearing voices (1)
- Feeling mask on face (2)
- Being with family (3)
- Nothing (4)
- Feeling breathing tube (5)
- Feeling pain (6)
- Being in the ICU (7)
- Other (8)

* Specify the first thing you remember after waking up:

brice_frstmemspec

Modified Brice

* Do you remember anything between going to sleep and waking up? brice_slpmem

- Yes (1)
- No (2)

* If yes, select all that apply:

- Hearing voices brice_voice
- Unable to move or breathe brice_mvmt
- Feeling pain brice_pain
- Anxiety/stress brice_anx
- Sensation of the breathing tube brice_tube
- Other brice_other

* Specify anything else you remember from when you were asleep:

brice_otherspec

* Did you dream during your time in the ICU? brice_dream

- Yes (1)
- No (2)

* If yes, what did you dream about?

brice_dreamspec

* Were your dreams disturbing to you? brice_distdream

- Yes (1)
- No (2)

* What was the worst thing about your ICU stay? brice_worsticu

- Anxiety (1)
- Recovery process (2)
- Awareness (3)
- Pain (4)
- Unable to carry out usual activities (5)
- Other (6)

* Specify the worst thing about your ICU stay:

brice_worsticuspec

BRICE complete

- brice_complete

Protocol Deviation

Protocol deviation

* Date deviation occurred:

pd_devdt

* Date deviation discovered:

pd_devrepdt

* Type of deviation: pd_devtype

- Eligibility error (1)
- Drug error (2)
- Incorrect treatment assignment (3)
- Other (888)

* Type of drug error: pd_drugtype

- Wrong dose (1)
- Wrong infusion duration (2)
- Wrong drug administered (3)
- More than 4 hours from randomization to start of drug (4)
- Other (888)

* Please specify:

pd_other

* Describe deviation:

pd_desc

* Describe steps taken to resolve the deviation and prevent future occurrences:

pd_resolution

* Was study drug temporarily or permanently discontinued as a result of this deviation? pd_drugstop

- Yes (1)
- No (2)

* Was an adverse event reported as a result of this deviation? pd_ae

- Yes (1)
- No (2)

Protocol deviation ID:

pd_id

Protocol Deviation

PD complete pd_complete

PD version

pd_version
