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

Death date

Death Date:

deathdt

Study participation

- VIOLET study_violet

  Enrollment date

  study_violetenrolldt

  Discontinuation date

  study_violetdiscondt

Randomization

RAND complete

- rand__fcomplete

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

Attributes

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

Ventilator History

VENTHX complete
☐ venthx__fcomplete

* Was the patient on mechanical ventilation (assisted breathing) at the time of randomization? venthx_atrand
  - Yes (1)
  - No (0)

  * Was mechanical ventilation (assisted breathing) started on or before study day 28? venthx_start
    - Yes (1)
    - No (0)

    * First date of mechanical ventilation (assisted breathing):
    venthx_startdt

* Was patient alive and on unassisted breathing (no longer on mechanical ventilation) on study day 28? venthx_uabd28
  - Yes (1)
  - No (0)

  * Last date patient was on mechanical ventilation (assisted breathing):
  venthx_lastdt

Study termination and post-discharge

TERM complete
☐ term__fcomplete

* Was the patient permanently withdrawn from the trial (study completion does not qualify as withdrawal)? term_withdrawn
  - Yes (1)
  - No (0)

  * Date of withdrawal:
  term_withdrawndt

  * Reason for withdrawal:
  term_withdrawnspec

Study hospital discharge

* Was the patient discharged alive from the study hospital (through day 90)? term_dischd90
  - Yes (1)
  - No (0)

  * Date of study hospital discharge:
  term_dischd90dt

  * Was the patient on mechanical ventilation (assisted breathing) at discharge? term_ventdisch
    - Yes (1)
    - No (0)

* Study hospital discharge disposition: term_dischdisp Attributes
  - Home (1)
  - LTAC (2)
  - SNF (3)
  - Acute rehab facility (4)
  - Acute care hospital (5)
  - Long-term care facility (6)
  - Other (888)

  * Specify:
    term_dischdispspec

  * Was the patient ultimately discharged to "home" prior to day 90? term_pafdisch
    - Yes (1)
    - No (0)

    * Date of discharge to home from post acute facility:
      term_pafdischdt

Day 90 status and safety

Complete these questions at time of death, or after day 90 follow-up.

* Day 90 vital status: term_status
  - Dead (1)
  - Alive (2)

  * Date of death
    term_deathdt

  * Location at Day 90 term_loc
    - Home (1)
    - LTAC (2)
    - SNF (3)
    - Acute rehab facility (4)
    - Acute care hospital (5)
    - Long term care facility (6)
    - Other (888)

    * Specify:
      term_locspec

* Did the patient have a new diagnosis of kidney stone between randomization and study day 90? term_kidneystoneyn
  - Yes (1)
  - No (0)

  * Date of first kidney stone between randomization and day 90:
    term_kidneystonedt

  * Was kidney stone information verified? term_kidneystonver
    - Verified as correct (1)
    - Unable to verify (2)

* Did the patient experience a fall between randomization and day 90? Attributes
  - Yes (1) term_fallyn
  - No (0)

  * Date of first fall between randomization and day 90:
    term_falldt

* Did the patient experience any fractures between randomization and day 90? term_fracyn
  - Yes (1)
  - No (0)

  * Were any of the fractures related to a fall? term_fracrelated
    - Yes (1)
    - No (0)

    * Date of first fall related fracture
      term_fracdt

    * Was the fall related fracture verified? term_fracverify
      - Verified as correct (1)
      - Unable to verify (2)

Patient reconsent

RC complete

☐ rc__fcomplete

* Was written consent obtained from the patient during study hospitalization? rc_reconsentyn
  - Yes (1)
  - No (0)

* If not, why? rc_reconsentnreas
  - 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:
    rc_reconsentnreasspec

Day 90 EQ-5D-5L

EQ90 complete

☐ eq90__fcomplete

* This data was obtained from: eq90_source
  - Patient (1)
  - Surrogate (2)
  - Unknown (3)

Attributes

* Mobility eq90_mobility
- I have no problems walking (1)
- I have slight problems walking (2)
- I have moderate problems walking (3)
- I have severe problems walking (4)
- I am unable to walk (5)
- *Not answered* (-99)

* Self-care eq90_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 have severe problems washing or dressing myself (4)
- I am unable to wash or dress myself (5)
- *Not answered* (-99)

* Usual Activities *(e.g. work, study, housework, family or leisure activities)* eq90_activities
- 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 have severe problems doing my usual activities (4)
- I am unable to do my usual activities (5)
- *Not answered* (-99)

* Pain / Discomfort eq90_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* (-99)

* Anxiety / Depression eq90_anxiety
- 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* (-99)

Screening

Inclusion / Exclusion

IE complete

☐ ie__fcomplete

* **Did patient meet the following inclusion criteria** ie_incl

i. Age ≥ 18 years
ii. Intent to admit to ICU from ED, hospital ward, operating room or outside facility?
iii. Has one or more acute risk factors for ARDS and mortality contributing directly to the need for ICU admission

○ Yes (1)
○ No (0)

Reasons for exclusion *(select all that apply)*:

☐ Not Excluded ie_notexcl

☐ Unable to Randomize within 12 hours of ICU admission decision ie_rand

- ○ Study team unavailable (1)
- ○ Unable to measure Vit D level (2)
- ○ Patient unable to consent and surrogate unavailable (3)
- ○ Transferred from referring hospital ICU (4)
- ○ Other (888)

ie_randreas

* Specify:
ie_randreasspec _____

☐ Unable to take study medication by mouth or enteral tube ie_med

☐ Baseline serum calcium > 10.2 mg/dL (2.54 mmol/L) or ionized calcium > 5.2 mg/dL (1.30 mmol/L) ie_cal

☐ Known kidney stone in past year or history of multiple (> 1) prior kidney stone episodes ie_kidneyst

☐ Decision to withhold or withdraw life-sustaining treatment (patients are still eligible if they are committed to full support except cardiopulmonary resuscitation if a cardiac arrest occurs) ie_withdraw

☐ Expect < 48 hour survival ie_survival

☐ Mechanical ventilation exclusions (if no other risk factor present) ie_mechvent

☐ Prisoner ie_prisoner

☐ Pregnancy ie_pregnancy

☐ Greater than 72 hours since hospital presentation (or > 3 calendar days since hospital presentation if transferred with no time stamp) ie_hosp3days

☐ Inability to obtain informed consent ie_consent

- ○ Treating physician refusal (1)
- ○ Patient/surrogate refusal (2)
- ○ Study team unavailable (3)
- ○ Unable to locate surrogate (4)
- ○ Interpreter/translator required but not available (5)

ie_consentreas

☐ Not excluded but not enrolled ie_nene

* Reason not enrolled:

ie_nenespec

Consent

CONS complete

☐ cons__fcomplete

* Has informed consent been obtained for participation in the VIOLET study? cons_consyn
  - ○ Yes (1)
  - ○ No (0)

  * Was initial consent obtained from the patient or from a surrogate? cons_constype
    - ○ Subject (1)
    - ○ Surrogate (2)

* Was consent obtained for the collection of samples for future genetic research in ARDS? cons_genards
  - ○ Yes (1)
  - ○ No (0)

* Was consent obtained for the collection of samples for future genetic research for other conditions? cons_genothers
  - ○ Yes (1)
  - ○ No (0)

Vitamin D screening

VITD complete

☐ vitd__fcomplete

* Is the patient vitamin D deficient based on screening (25OHD level <20 ng/mL)? vitd_deficient
  - ○ Yes (1)
  - ○ No (0)

  * Method used for 25OHD level vitd_method
    - ○ Qualigen (1)
    - ○ Clinical lab (2)

      * Is sample plasma or serum? vitd_sampletype
        - ○ Plasma (1)
        - ○ Serum *(only for sites with Siemens device)* (2)

Date and time of blood draw for vitamin D screening:

* vitd_dt * vitd_tm

* First 25OHD level

_____ ng/mL vitd_25ohd1

* Second 25OHD level

_____ ng/mL vitd_25ohd2

Third 25OHD level

_____ ng/mL vitd_25ohd3

* Average of the 2 FastPack test results (values used to determine eligibility; if a FastPack value is < 12.9, use 12.9 when averaging):

_____ ng/mL vitd_vitavg

Vitamin D supplements

* Was the patient taking any vitamin D supplements or medications in the 30 days prior to the current hospitalization? vitd_vitd30d
  - ○ Yes (1)
  - ○ No (0)
  - ○ *Unknown* (-9)

  * Average daily dose: vitd_vitddose* ○ (1) IU ○ (2) mcg vitd_vitddoseunit

  * Was the vitamin D supplement taken within the past week? vitd_vitdweek
    - ○ Yes (1)
    - ○ No (0)
    - ○ *Unknown* (-9)

Prior vitamin D clinical result

* Is there a vitamin D level available in the clinical record from the previous 6 months? vitd_clinyn
  - ○ Yes (1)
  - ○ No (0)

    * Most recent clinically available vitamin D level: vitd_clin

      _____ ng/mL

Eligibility status: scrstat_scrstatus
- ○ In screening (1)
- ○ Failed screening (2)
- ○ Passed screening (3)

Risk factors

RISK complete
- ☐ risk__fcomplete

* Select all acute risk factors for ARDS and mortality contributing directly to the need for ICU admission below:

Pulmonary

- ☐ Pneumonia risk_pneumonia
- ☐ Aspiration risk_aspiration
- ☐ Smoke inhalation risk_smoke
- ☐ Lung contusion risk_lungcont
- ☐ Mechanical ventilation risk_mechvent

Extra-pulmonary

- ☐ Shock risk_shock

  * Indicate presumed etiology(ies) of shock:

    - ☐ Infection/sepsis risk_shockinfec

- ☐ Cardiogenic risk_shockcardio
- ☐ Anaphylactic risk_shockanaphyl
- ☐ Hemorrhagic traumatic risk_shockhemtrau
- ☐ Hemorrhagic non-traumatic risk_shockhemnontrau
- ☐ Other risk_shockother
  - * Please specify: risk_shockotherspec

☐ Sepsis risk_sepsis

* Indicate presumed source(s) of infection:

- ☐ Thorax risk_sepsisthorax
- ☐ Abdomen risk_sepsisabdom
- ☐ Skin or soft tissue risk_sepsisskin
- ☐ Bacterial meningitis risk_sepsismening
- ☐ Urinary tract risk_sepsisutract
- ☐ Central line infection risk_sepsiscline
- ☐ Other risk_sepsisother
  - * Please specify: risk_sepsisotherspec

☐ Pancreatitis risk_pancreat

Other screening data

SCR complete

☐ scr__fcomplete

Date and time of "intent to admit to ICU":

* scr_icuintentdt * scr_icuintenttm

* Patient age (screen fails):

_____ years scr_agescr

* Patient age (randomized patients):

_____ years scr_age

* Location when intent to admit to ICU criteria met: scr_admloc

- ○ Referring hospital (1)
- ○ Study hospital ED (2)
- ○ Study hospital ward (3)
- ○ Study hospital OR (4)

* Month patient met inclusion criteria scr_inclmonth

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

Baseline - Day 0

Study drug dosing

SDD complete

☐ sdd__fcomplete

* Was study drug administered? sdd_drugyn

○ Yes (1)
○ No (0)

Date and time of administration:

* sdd_drugdt * sdd_drugtm

* Indicate reason(s) why study drug was not administered. *(Select all that apply)*

☐ Consent withdrawn sdd_conswithdraw

☐ Study drug unavailable sdd_drugunavail

☐ Patient npo sdd_npo

☐ No naso-gastric tube sdd_nasogastric

☐ Patient unavailable (procedure/OR/diagnostic testing) sdd_ptunavail

☐ Patient unstable (describe) sdd_unstable

* Specify:
sdd_unstablespec

* Was study drug tolerated (consumed entire drug volume with no *nausea*, *vomiting*, or *other complaints* within 60 minutes after dose)? sdd_drugtol

○ Yes (1)
○ No (0)

* Indicate reason(s) why study drug was not tolerated. *(Select all that apply)*

☐ Did not like the taste after consuming a partial dose sdd_nttaste

☐ Experienced nausea after dosing sdd_ntnausea

☐ Vomited within 60 minutes after dosing sdd_ntvomit

☐ Had chest or abdominal pain (or heart burn) after dosing sdd_ntheartburn

☐ Other sdd_ntother

* Specify:
sdd_ntotherspec

Baseline labs and medications

BLLABS complete

☐ bllabs__fcomplete

* Total serum calcium level: bllabs_caser

_____ mg/dL

* Ionized calcium level:
bllabs_caion

* ○ mg/dL (1)
○ mmol/L (2)
bllabs_caionunits

* WBC *(If available within the 12 hours prior to randomization)*:

_____ /mm^3 bllabs_wbc

* Lactate *(If available within the 12 hours prior to randomization)*:

_____ mmol/L bllabs_lactate

* Was patient taking any vitamin D supplements or medications in the 30 days prior to the current hospitalization? bllabs_vitd30d
○ Yes (1)
○ No (0)
○ *Unknown* (-9)

bllabs_vitd variables were disabled and replaced by the vitd_vitd variables in the Screening form

* Average daily dose: _____ * ○ IU (1) ○ mcg (2) bllabs_vitddoseunit
bllabs_vitddose

* Was the vitamin D supplement taken within the past week? bllabs_vitdweek
○ Yes (1)
○ No (0)
○ *Unknown* (-9)

* Was patient taking calcium supplements in the 30 days prior to the current hospitalization? bllabs_ca30d
○ Yes (1)
○ No (0)
○ *Unknown* (-9)

* Average daily dose:

_____ mg bllabs_cadose

* Was the calcium supplement taken within the past week? bllabs_caweek
○ Yes (1)
○ No (0)
○ *Unknown* (-9)

* Was the patient taking a multivitamin (MVI) in the 30 days prior to the current hospitalization? bllabs_mvi30d
○ Yes (1)
○ No (0)
○ *Unknown* (-9)

* What was the MVI labeled for? bllabs_mvilabel
○ Women's Health (1)
○ Men's Health (2)
○ Senior Health (3)
○ None of the above (4)
○ *Unknown* (-9)

* Was the MVI taken within the past week? bllabs_mviweek
○ Yes (1)
○ No (0)
○ *Unknown* (-9)

Medical history

Baseline - Day 0

☐ medhx__fcomplete

* Is there a non-acute (pre-hospitalization) creatinine level available in the previous two years? medhx_creatyn

- ○ Yes (1)
- ○ No (0)

* Most recent pre-hospitalization creatinine level within the last 2 years:

_____ mg/dL medhx_creat

* Is the patient on home mechanical ventilation (non-invasive ventilation or via tracheostomy)? medhx_homevent

- ○ Yes (1)
- ○ No (0)

* Is the home mechanical ventilation used solely for sleep-disordered breathing? medhx_homeventsleep

- ○ Yes (1)
- ○ No (0)

* Height: medhx_height _____ * ○ (1) inches ○ (2) cm medhx_heightunit

* Measured weight: _____ * ○ (1) lbs ○ (2) kg medhx_weightunit
medhx_weight

Vital signs (most recent prior to randomization):

Blood pressure:

* Systolic: medhx_sbp _____ mmHg

* Diastolic: medhx_dbp _____ mmHg

* Heart rate: medhx_hr
_____ beats per min

* Respiratory rate: medhx_rate
_____ breaths per min

* Temperature: _____ * ○ (1) C ○ (2) F medhx_tempunit
medhx_temp

* O_2 sat:

_____ % medhx_oxygen

* FiO_2:

_____ (decimal) medhx_fio2

* Date of hospital admission:
medhx_hospadmdt

* ICU admission service medhx_icutype

- ○ Medical (1)
- ○ Surgical scheduled (2)
- ○ Surgical unscheduled (3)
- ○ Trauma (4)
- ○ Other (888)
- ○ Not admitted to ICU (6)

* Specify:
medhx_icutypespec _____

Baseline - Day 0

* Date of ICU admission
medhx_icuadmtdt

* Pre-hospital level of care: medhx_prehosp
- ○ Home independently (1)
- ○ Home with help (2)
- ○ Home with professional help (3)
- ○ Intermediate care or rehab facility (e.g. goal is to get patient better) (4)
- ○ Nursing facility (e.g. goal is to meet patient's ongoing needs) (5)
- ○ Acute care hospital (6)
- ○ Homeless or living in a temporary shelter (7)
- ○ Adult family home or other non-medical institutional setting (8)
- ○ Other (888)

* Specify:
medhx_prehospspec

Charlson [g]

CHARLG complete
☐ charlg__fcomplete

* Is chronic health information available? charlg_yn
- ○ Yes (1)
- ○ No (0)

Charlson [q]

CHARL complete ☐ charl__fcomplete

Indicate whether each condition was present at hospital admission and **prior** to randomization.

		Yes	No	
*	AIDS *(do not include HIV-positive without AIDS criteria)*	○	○	charl_aids
*	Leukemia *(AML, CML, ALL, multiple myeloma)*	○	○	charl_leuk
*	Malignant lymphoma	○	○	charl_lymph
*	Hemiplegia	○	○	charl_hemiplegia
*	Cerebrovascular disease	○	○	charl_cerebvasc
*	A prior myocardial infarction	○	○	charl_myoinfarc
*	Congestive heart failure	○	○	charl_congheart
*	Peripheral vascular disease	○	○	charl_perivasc
*	Dementia	○	○	charl_dementia
*	COPD	○	○	charl_copd
*	Connective tissue disease	○	○	charl_contis
*	Peptic ulcer disease	○	○	charl_ulcer

* Solid tumor charl_tumor
  - No solid tumor present (0)
  - Solid tumor present (exclude if > 5 years from diagnosis) (1)
  - Solid tumor with metastasis present (ever) (2)

* Liver disease charl_liver
  - No liver disease present (0)
  - Mild liver disease present (without portal hypertension, includes chronic hepatitis) (1)
  - Moderate/severe liver disease present (2)

* Diabetes mellitus *(DM)* charl_diabetes
  - No DM present (0)
  - Uncomplicated DM present (no end organ damage present) (1)
  - DM with end organ damage present (excludes diet controlled alone) (2)

* Moderate to severe kidney disease charl_kidney
  - No moderate to severe kidney disease present (0)
  - Moderate to severe kidney disease present (Cr > 3, ESRD, chart diagnosis of CKD stage 5 (eGFR < 15 mL/min/1.73m^2) not on dialysis) (1)
  - Moderate to severe kidney disease present and patient is dialysis dependent (2)

SOFA

SOFA complete

☐ sofa__fcomplete

Collect these values, if available, from the 24 hours before randomization. If no values are available in that time window, you may use the closest value up to 6 hours after randomization.

* Lowest P/F:

sofa_pf

* PaO_2:

_____ mmHg sofa_pao2

* FiO_2:

_____ (decimal) sofa_fio2

Glasgow Coma Score (GCS):

Use the last non-sedated Glasgow Coma Score (GCS) available. If no non-sedated values are available, use the most recent GCS score.

* Is the patient on a sedative or neuromuscular blocker? sofa_gcssedate
  - Yes (1)
  - No (0)

* Eye opening score: sofa_gcseye
  - None (1)
  - To pain (2)
  - To voice (3)
  - Spontaneous (4)

* Motor response score: sofa_gcsmotor
  - ○ Flaccid (1)
  - ○ Abnormal extension (2)
  - ○ Abnormal flexion (3)
  - ○ Flexion withdrawal (4)
  - ○ Localizes to pain (5)
  - ○ Obeys commands (6)

* Verbal response score: sofa_gcsverbal
  - ○ None, or generally unresponsive on ventilator (1)
  - ○ Incomprehensible (2)
  - ○ Inappropriate, or questionably oriented if on ventilator (3)
  - ○ Confused (4)
  - ○ Oriented, or appears oriented if on ventilator (5)

* Lowest platelets:

_____ $10^3/\mu L$ ($\times 1000/mm^3$) sofa_platl

* Highest bilirubin:

_____ mg/dL sofa_bilih

* Highest creatinine level:

_____ mg/dL sofa_creath

* Lowest MAP:

_____ mmHg *(calculate if not available)* sofa_mapl

* Vasopressors (any infusions lasting > 1 hour): sofa_vasoyn
  - ○ Yes (1)
  - ○ No (0)

* Record highest infusion rate of each lasting > 1 hour:

  - ☐ Dobutamine * _____ µg/kg/min sofa_vasodobutyn sofa_vasodobut
  - ☐ Dopamine * _____ µg/kg/min sofa_vasodopyn sofa_vasodop
  - ☐ Epinephrine * _____ µg/kg/min sofa_vasoepiyn sofa_vasoepi
  - ☐ Norepinephrine * _____ µg/kg/min sofa_vasonorepiyn sofa_vasonorepi
  - ☐ Neosynephrine * _____ µg/kg/min sofa_vasoneosynyn sofa_vasoneosyn
  - ☐ Vasopressin * _____ units/min sofa_vasovasopyn sofa_vasovasop

LIPS

LIPS complete

☐ lips__fcomplete

* Did the patient undergo high-risk surgery during this hospitalization? lips_hrsurgyn
  - ○ Yes (1)
  - ○ No (0)

lips_hrsurgtype

* What type of high-risk surgery:
  - Orthopedic spine (1)
  - Acute abdomen (2)
  - Cardiac (3)
  - Aortic vascular (4)

* Did the patient undergo emergency surgery during this hospitalization (this may overlap with high-risk)? lips_emsurgyn
  - Yes (1)
  - No (0)

Please select *Yes* or *No* for each of the following risk factors:

* Obesity (BMI ≥ 30 in past 6 months): lips_obeseyn
  - Yes (1)
  - No (0)
  - *Information unavailable* (777)

* Chemotherapy (in the past 6 months): lips_chemoyn
  - Yes (1)
  - No (0)
  - *Information unavailable* (777)

* Alcohol abuse (ever): lips_alcoholyn
  - Yes (1)
  - No (0)
  - *Information unavailable* (777)

Please select *Yes* or *No* for each of the following risk factors for the current hospitalization:

* Near drowning: lips_drownyn
  - Yes (1)
  - No (0)

* Traumatic brain injury: lips_traumabrainyn
  - Yes (1)
  - No (0)

* Multiple fractures (defined as two long bones, or one long bone + pelvis): lips_multifracyn
  - Yes (1)
  - No (0)

Please select *Yes* or *No* for each of the following risk factors with regard to the 24 hours before randomization. If no values are available for this time frame, you may use values up to 6 hours after randomization.

* Tachypnea (respiratory rate > 30 breaths / min): lips_respyn
  - Yes (1)
  - No (0)

* O_2 saturation < 95%: lips_oxyyn
  - Yes (1)
  - No (0)

* FiO_2 >35% (or >4L O_2/min)? lips_fio2yn
  - Yes (1)
  - No (0)

lips_phyn

* Acidosis (blood pH level < 7.35 arterial or < 7.32 venous)
  - ○ Yes (1)
  - ○ No (0)
  - ○ *Information unavailable* (777)

* Please provide the blood albumin level closest to the time of randomization:

_____ g/dL lips_albumin

ARDS assessment [g]

ARDSG complete

☐ ardsg__fcomplete

* Was the patient on mechanical ventilation this study day? ardsg_ventyn
  - ○ Yes (1)
  - ○ No (0)

ARDS assessment [q]

ARDS complete

☐ ards__fcomplete

* Is there an ABG available between 0200 and 0800? ards_abgyn
  - ○ Yes (1)
  - ○ No (0)

    * PaO_2 for lowest P/F ratio: ards_abgypao2

      _____ mmHg

    * FiO_2 for lowest P/F ratio: ards_abgyfio2

      _____ (decimal)

    * PEEP at time of lowest P/F: ards_abgypeep

      _____ cm H_2O

    * Are there SpO_2 values ≥80% and ≤96% during this time period? ards_abgnspo2yn
      - ○ Yes (1)
      - ○ No (0)

        * SpO_2 corresponding to lowest imputed P/F:

          _____ % ards_abgnspo2

        * FiO_2 corresponding to lowest imputed P/F:

          _____ (decimal) ards_abgnfio2

        * PEEP at time of lowest imputed P/F:

          _____ cm H_2O ards_abgnpeep

P/F or imputed P/F:

ards_pf

_____

If P/F (or imputed P/F) < 300, $FiO_2 \geq 0.4$, and PEEP ≥ 5:

ards_hypox

* Is hypoxemia valid, acute, and not fully explained by CHF or fluid overload?
  - Yes (1)
  - No (0)
  - P/F does not meet high-altitude ARDS cut off (2)

* Is CXR or CT (± 1 day) consistent with ARDS? ards_cxrcons
  - Yes (1)
  - No (0)
  - Equivocal (2)
  - Met ARDS criteria on previous day (3)
  - P/F does not meet high-altitude ARDS cut-off (4)

Baseline EQ-5D-5L

EQBL complete

☐ eqbl__fcomplete

* This data was obtained from: eqbl_source
  - Patient (1)
  - Surrogate (2)
  - Unknown (3)

* Mobility eqbl_mobility
  - I have no problems walking (1)
  - I have slight problems walking (2)
  - I have moderate problems walking (3)
  - I have severe problems walking (4)
  - I am unable to walk (5)
  - *Not answered* (-99)

* Self-care eqbl_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 have severe problems washing or dressing myself (4)
  - I am unable to wash or dress myself (5)
  - *Not answered* (-99)

* Usual activities *(e.g. work, study, housework, family or leisure activities)* eqbl_activities
  - 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 have severe problems doing my usual activities (4)
  - I am unable to do my usual activities (5)
  - *Not answered* (-99)

* Pain / discomfort eqbl_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* (-99)

* Anxiety / depression eqbl_anxiety
  - 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* (-99)

Sample collection

SAMP complete

☐ samp__fcomplete

* 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

Day 1 - 7

ARDS assessment [g]

ARDSG complete

☐ ardsg__fcomplete

* Was the patient on mechanical ventilation this study day? ardsg_ventyn

- ○ Yes (1)
- ○ No (0)

ARDS assessment [q]

ARDS complete

☐ ards__fcomplete

* Is there an ABG available between 0200 and 0800? ards_abgyn

- ○ Yes (1)
- ○ No (0)

* PaO_2 for lowest P/F ratio: ards_abgypao2

_____ mmHg

* FiO_2 for lowest P/F ratio: ards_abgyfio2

_____ (decimal)

* PEEP at time of lowest P/F: ards_abgypeep

_____ cm H_2O

* Are there SpO_2 values ≥80% and ≤96% during this time period? ards_abgnspo2yn

- ○ Yes (1)
- ○ No (0)

* SpO_2 corresponding to lowest imputed P/F: ards_abgnspo2

_____ %

* FiO_2 corresponding to lowest imputed P/F: ards_abgnfio2

_____ (decimal)

* PEEP at time of lowest imputed P/F: ards_abgnpeep

_____ cm H_2O

P/F or imputed P/F:

ards_pf

If P/F (or imputed P/F) < 300, FiO_2 ≥ 0.4, and PEEP ≥ 5:

* Is hypoxemia valid, acute, and not fully explained by CHF or fluid overload? ards_hypox

- ○ Yes (1)
- ○ No (0)
- ○ P/F does not meet high-altitude ARDS cut off (2)

ards_cxrcons

Day 1 - 7

* Is CXR or CT (± 1 day) consistent with ARDS?
  - ○ Yes (1)
  - ○ No (0)
  - ○ Equivocal (2)
  - ○ Met ARDS criteria on previous day (3)
  - ○ P/F does not meet high-altitude ARDS cut-off (4)

Organ failure

ORGAN complete

☐ organ__fcomplete

* Was the patient on any vasopressors (infusion lasting >1 hour) this study day? organ_vasoyn
  - ○ Yes (1)
  - ○ No (0)

  * Record highest infusion rate of each lasting > 1 hour:

    - ☐ Dobutamine * _____ µg/kg/min organ_vasodobutyn organ_vasodobut
    - ☐ Dopamine * _____ µg/kg/min organ_vasodopyn organ_vasodop
    - ☐ Epinephrine * _____ µg/kg/min organ_vasoepiyn organ_vasoepi
    - ☐ Norepinephrine * _____ µg/kg/min organ_vasonorepiyn organ_vasonorepi
    - ☐ Neosynephrine * _____ µg/kg/min organ_vasoneosynyn organ_vasoneosyn
    - ☐ Vasopressin * _____ units/min organ_vasovasopyn organ_vasovasop

* Highest creatinine for this calendar day (if clinically available):

_____ mg/dL organ_creath

* Was there new dialysis or RRT this study day? organ_dialrrt
  - ○ Yes (1)
  - ○ No (0)
  - ○ N/A, new RRT reported on a previous study day (2)

Labs and medications

LABS complete

☐ labs__fcomplete

* Was the patient given vitamin D medication this study day? labs_vitd
  This includes anything ordered as "vitamin D" 1000 IU or more; it does not include vitamin D as part of an MVI or parenteral nutrition.
  - ○ Yes (1)
  - ○ No (0)
  - ○ *Unknown* (2)

  * Total oral vitamin D medications:

labs_vitdtotal

  * ○ IU (1)
    ○ mcg (2)

labs_vitdtotalunits

Collect lab values, if available, closest to 0800. Day 1 - 7

* Total serum calcium level *(required on day 3 in first 300 patients, otherwise if clinically available)*:

_____ mg/dL labs_caser

* Ionized calcium level:

labs_caion

* ○ mg/dL (1)
  ○ mmol/L (2) labs_caionunits

* Serum albumin

_____ g/dL labs_albumin

Day 8 - 14

Labs and medications

LABS complete

☐ labs__fcomplete

* Was the patient given vitamin D medication this study day? labs_vitd

This includes anything ordered as "vitamin D" 1000 IU or more; it does not include vitamin D as part of an MVI or parenteral nutrition.

- ○ Yes (1)
- ○ No (0)
- ○ *Unknown* (2)

* Total oral vitamin D medications:

labs_vitdtotal

* ○ IU (1)
○ mcg (2)

labs_vitdtotalunits

Collect lab values, if available, closest to 0800.

* Total serum calcium level *(required on day 3 in first 300 patients, otherwise if clinically available)*:

_____ mg/dL labs_caser

* Ionized calcium level: labs_caion

_____

* ○ mg/dL (1)
○ mmol/L (2)

labs_caionunits

* Serum albumin

_____ g/dL labs_albumin

Adverse Event

Adverse event

AE complete

☐ ae__fcomplete

Date and time of adverse event:

* ae_dt * ae_tm

* 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 (0)

* Was the adverse event related to study drug administration? ae_reldrug

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

* Was the adverse event unexpected (not listed in the investigator brochure)? ae_unexpected

- ○ Yes (1)
- ○ No (0)

* 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

Adverse event ID:

ae_id

Adverse Event

Protocol Deviation

Protocol deviation

PD complete

☐ pd__fcomplete

* 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)
- ○ Sample error (4)
- ○ Consent error (5)
- ○ Other (888)

* Type of drug error: pd_drugtype

- ○ Wrong dose (1)
- ○ Wrong drug administered (3)
- ○ More than 2 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 (0)

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

- ○ Yes (1)
- ○ No (0)

Protocol deviation ID:

pd_id

Protocol Deviation