

Screening and patient inclusion details

To the including physician Please complete the screening and inclusion details below for the patient you wish to include in the trial.

It is very important that you deliver the randomisation envelope with the STUDY ID and treatment allocation to TRAUMOX2 personnel at the hospital.

Thank you for contributing to the TRAUMOX2 trial!

SCREENING FOR PATIENT INCLUSION

Eligibility criteria

- Age \geq 18 years
- Blunt or penetrating trauma
- Direct transfer from the scene of accident to the trauma centre
- Trauma team activation
- Expected hospital length of stay for at least 24 hours
- No cardiac arrest before or on admission
- No suspicion of carbon monoxide intoxication (ALWAYS CHECK OFF ALL ELIGIBILITY CRITERIA)

Date of randomisation

_____ (DD-MM-YYYY)

STUDY ID

_____ (THE STUDY ID IS FOUND OUTSIDE AND INSIDE OF THE RANDOMISATION ENVELOPE)

Was the patient excluded after randomisation?

- No
- Yes

Why was the patient excluded?

- Patient < 18 years of age
- Suspicion of carbon monoxide intoxication
- Cardiac arrest before or on admission
- Secondary transfer
- Secondary survey reveals no/minor injuries and an expected discharge of the patient < 24 hours
- The enrolling physician did after randomisation not anymore expect a hospital length of stay for at least 24 hours
- No trauma team was activated/trauma team activation was cancelled
- Lack of personnel
- Excluded due to going to a non-participating trauma centre
- Other

Describe why other was chosen as a reason for excluding the patient from the study

INCLUSION DETAILS

Pre-hospital or in-hospital inclusion?

- Pre-hospital
 In-hospital

From which pre-hospital base?

- ALB 1 og 2 - City, København
 ALB 3 - Syd, Hvidovre
 ALB 4 - Nord, Hillerød
 ALB 5 - Midt, Herlev
 Ringsted Akutlægehelikopter
 Billund Akutlægehelikopter
 Skive Akutlægehelikopter
 ALB Odense
 ALB Aarhus
 ALB Silkeborg
 ALB Horsens
 ALB Randers
 HEMS and physician cars dispatchers, Rotterdam, The Netherlands

To which trauma centre?

- Rigshospitalet, Copenhagen, Denmark
 Odense Universitetshospital, Odense, Denmark
 Aarhus Universitetshospital, Aarhus, Denmark
 Emergency ward of Erasmus MC, Rotterdam, The Netherlands

Which trauma centre?

- Rigshospitalet, Copenhagen, Denmark
 Odense Universitetshospital, Odense, Denmark
 Aarhus Universitetshospital, Aarhus, Denmark
 University Hospital of Cologne, Cologne, Germany
 Erasmus MC, Rotterdam, The Netherlands

Airway at inclusion?

- Non-intubated
 Intubated

Randomisation group?

- Restrictive oxygen strategy
 Liberal oxygen strategy

PATIENT INFORMATION

Danish CPR/replacement CPR?

- No
 Yes

Patient name

 (Type "u" if you don't know the name; short version of a patient name is acceptable)

Sex

- Male
 Female

Patient's date of birth known?

- No
 Yes

Date of birth

 (DD-MM-YYYY)

Age at inclusion

(A calculated age at inclusion will appear after entering date of randomisation and date of birth)

Estimated age at inclusion

CPR number or replacement CPR number?

- CPR
 Replacement CPR

CPR number

(CPR number WITHOUT hyphen)

Replacement CPR number

(Replacement CPR number WITHOUT hyphen)

TRAUMA DETAILS

Dominating type of injury

- Blunt
 Penetrating

Mechanism of injury

- Traffic: Motor vehicle accident
 Traffic: Motorcycle accident
 Traffic: Bicycle accident
 Traffic: Pedestrian
 Traffic: Other (e.g. ship, airplane or railway train)
 Shot by handgun, shotgun, rifle or other firearm of any calibre
 Stabbed by knife, sword, dagger, other pointed or sharp object
 Struck or hit by blunt object
 Fall: 0-2 metres
 Fall: 2-4 metres
 Fall: >4 metres
 Blast/explosion
 Other
 Unknown

Short description of other mechanism of injury

NAME AND SIGNATURE BY THE INCLUDING PHYSICIAN

Name of the including physician

Signature by the including physician

For Danish sites, this signature also confirms that the including physician has informed the study guardian about the trial participant's medical condition

Patient characteristics and history after inclusion: Investigator

Record ID

CHARACTERISTICS AND DEMOGRAPHICS

Patient name

E-mail

(For follow-up purposes)

Phone number

(For follow-up purposes)

Do you have the CPR number at this time?

- No
 Yes

CPR number

(CPR number without hyphen)

Was the patient at any point registered with an
"erstatnings" CPR number?

- No
 Yes

"Erstatnings" CPR number

("Erstatnings" CPR number without hyphen)

Date of birth

(DD-MM-YYYY)

Date of inclusion

(DD-MM-YYYY)

Age at inclusion

(Age will appear after entering data on date of
birth and date of inclusion (if the calculated age
is < 18, you should recheck your date entries in
REDCap))

Sex

- Male
 Female

Weight

(Kilograms without decimals)

Height

(Meters with two decimals)

Body Mass Index (BMI)

(BMI will appear after entering data on height and weight)

HISTORY

Active smoker

- No
 Yes
-

Comorbidities prior to trauma

- Lung disease
 Cardiovascular disease
 Other disease(s)
 None
(Multiple comorbidities may be marked; a positive COVID-19 test at admission can be marked if "Lung disease" is marked)
-

Mark the lung disease(s) the patient suffers from

- Chronic obstructive pulmonary disease (COPD)
 Asthma
 Lung fibrosis
 Lung cancer
 Positive COVID-19 test at admission
 Other
(Multiple lung diseases may be marked)
-

Mark the cardiovascular disease(s) the patient suffers from

- Hypertension
 Angina
 Atrial fibrillation
 Heart failure
 Coronary artery disease
 Other
(Multiple cardiovascular diseases may be marked)
-

What other disease(s)?

(Any additional medical disease that in itself would result in a classification ASA 2 or higher)

Is the patient in an active treatment for pneumonia at the time of admission?

- No
 Yes

Pre-hospital patient data: Investigator

Record ID

TIME POINTS AND PATIENT CHARACTERISTICS

Date and time of trauma

_____ (DD-MM-YYYY HH:MM)

Date and time of on-scene arrival

_____ (DD-MM-YYYY HH:MM)

Date and time of on-scene departure

_____ (DD-MM-YYYY HH:MM)

Was intubation performed pre-hospital?

- No
 Yes

Date and time of intubation

_____ (DD-MM-YYYY HH:MM)

Was the patient intubated before or after the randomised intervention was initiated?

- Before
 After

Did the patient die pre-hospital?

- No
 Yes

Date and time of death

_____ (DD-MM-YYYY HH:MM)

VITAL SIGNS

First recorded systolic blood pressure

_____ (mmHg)

First recorded diastolic blood pressure

_____ (mmHg)

Date and time of first recorded blood pressure measurement

_____ (DD-MM-YYYY HH:MM)

First recorded pulse

_____ (Number)

Date and time of first recorded pulse measurement

(DD-MM-YYYY HH:MM)

First recorded respiratory rate

(Number)

Date and time of first recorded respiratory rate measurement

(DD-MM-YYYY HH:MM)

First recorded SpO2

(%)

Date and time of first recorded SpO2 measurement

(DD-MM-YYYY HH:MM)

First recorded temperature

(Celsius with one decimal)

Date and time of first recorded temperature measurement

(DD-MM-YYYY HH:MM)

First recorded GCS

(Number)

Date and time of first recorded GCS measurement

(DD-MM-YYYY HH:MM)

DETAILS ON SUPPLEMENTAL OXYGEN PRIOR TO INCLUSION

Use of pre-hospital or in-hospital supplemental oxygen prior to randomisation?

- No
 Yes
(If it is unknown whether the patient received supplemental oxygen prior to inclusion, then use the missing data code)
-

Date and time for initiation of supplemental oxygen prior to randomisation

(DD-MM-YYYY HH:MM)

Highest SpO2 measured prior to randomisation?

(%)

Date and time for randomisation

(DD-MM-YYYY HH:MM; see date and time of randomisation in the data collection sheet)

Minutes of supplemental oxygen treatment before randomisation

(Number of minutes will appear after entering data on date and time of initiation of supplemental oxygen prior to inclusion and date and time of initiation of trial intervention)

Indication for supplemental oxygen treatment before randomisation

- Life-saving (SpO2 < 85%)
 Avoiding hypoxia (SpO2 < 90%)
 Routine treatment independent of SpO2
(Choose the best fit)

Supplementary oxygen administration form before randomisation

- Nasal cannula
 Non-rebreather mask
 Intubated

Initial oxygen flow chosen

(L/min)

Initial FiO2 chosen

(Two decimals)

Trauma centre patient data: Investigator

Record ID

PATIENT CHARACTERISTICS AND TIME POINTS

Type of transportation to the trauma centre

- Ground ambulance
- Helicopter ambulance
- A combination of ground ambulance and helicopter ambulance underway to the trauma centre
- Private vehicle
- Walk-in
- Police
- Other

Date and time of trauma call start

(DD-MM-YYYY HH:MM)

Was intubation performed in the trauma centre?

- No
- Yes

Date and time of intubation

(DD-MM-YYYY HH:MM)

Was the patient intubated before or after the randomised intervention was initiated?

- Before
- After

Was surgery performed in the trauma centre?

- No
- Yes

What type of surgery was performed?

- Neurosurgery
 - Cardiothoracic surgery
 - Abdominal surgery
 - Orthopaedic surgery
 - Urological surgery
 - Vascular surgery
 - Gynecological surgery
 - Other(s)
- (Multiple types of surgery performed may be marked)

Date and time of trauma call end

(DD-MM-YYYY HH:MM)

Duration of trauma call (minutes)

(Number of minutes will appear after entering data on date and time of trauma call start and date and time of trauma call end)

Did the patient die in the trauma centre?

- No
- Yes

Date and time of death

(DD-MM-YYYY HH:MM)

Where was the patient sent after initial treatment in the trauma centre?

- General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Operating Room
 Ward

(It will be possible to enter data on further time points in the instrument: "In-hospital patient data: Investigator")

Was the patient excluded from the study at any time after initially being included?

- No
 Yes

Date of exclusion

(DD-MM-YYYY)

What was the reason for excluding the patient from the study?

- Patient < 18 years of age
 Suspicion of carbon monoxide intoxication
 Cardiac arrest before or on admission
 Secondary transfer
 Secondary survey reveals no/minor injuries and an expected discharge of the patient < 24 hours
 The enrolling physician did after randomisation not anymore expect a hospital length of stay for at least 24 hours
 No trauma team was activated/trauma team activation was cancelled
 Lack of personnel
 Excluded due to going to a non-participating trauma centre
 Other

Describe why "other" was chosen as a reason for excluding the patient from the study

VITAL SIGNS

First recorded systolic blood pressure

(mmHg)

First recorded diastolic blood pressure

(mmHg)

Date and time of first recorded blood pressure measurement

(DD-MM-YYYY HH:MM)

First recorded pulse

(Number)

Date and time of first recorded pulse measurement

(DD-MM-YYYY HH:MM)

First recorded respiratory rate

(Number)

Date and time of first recorded respiratory rate measurement

(DD-MM-YYYY HH:MM)

First recorded SpO2

(%)

Date and time of first recorded SpO2 measurement

(DD-MM-YYYY HH:MM)

First recorded temperature

(Celsius with one decimal)

Date and time of first recorded temperature measurement

(DD-MM-YYYY HH:MM)

First recorded GCS

(Number)

Date and time of first recorded GCS measurement

(DD-MM-YYYY HH:MM)

INJURIES, ABBREVIATED INJURY SCALE (AIS) AND INJURY SEVERITY SCORE (ISS)

Injured body region(s)

- Head
- Neck
- Face
- Spine
- Thorax
- Abdomen
- Pelvis
- Extremity
- Other(s)

AIS codes

(Enter AIS codes seperated by semicolon without spaces, e.g. 4414111.3;442202.2;650206.3)

AIS: Head / Neck / Cervical spine

(AIS score)

AIS: Face

_____ (AIS score)

AIS: Thorax / Thoracic spine

_____ (AIS score)

AIS: Abdomen / Lumbar spine

_____ (AIS score)

AIS: Extremity

_____ (AIS score)

AIS: External incl. skin injuries and burns

_____ (AIS score)

Injury Severity Score (ISS)

_____ (ISS calculation based on AIS scores)

Data collection sheet: Investigator

Record ID

RANDOMISATION AND INTERVENTION TIME POINTS

Patient name

Randomised to
(mark one oxygen strategy box)

- Restrictive oxygen strategy
 Liberal oxygen strategy

Time of randomisation
(opening of the randomisation envelope)

(HH:MM)

Termination of study intervention
(8 hours after opening of the randomisation envelope)

(HH:MM)

If it is needed to fill in the data collection sheet with SpO2 and oxygen treatment values from the patient's medical record, use the value that are closest to the time slot. However, if there are more values around the time slot, use the median value.

If several arterial blood gasses (ABGs) have been drawn around the time slot for the 1st and 2nd ABG during the 8 hour intervention, use the PaO2 result from the ABG nearest to 1 hour and 6 hours after randomisation, respectively.

Data collection sheet: File upload

T0 (HOUR 0)

Was any data obtained for T0?

- No
 Yes

Date and time

(DD-MM-YYYY HH:MM)

Name of ward

- Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

SpO2 _____
(%)

Type of oxygen delivery None
 Nasal cannula
 Non-rebreather mask
 Intubated
(If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

Oxygen delivery _____
(L/min)

FiO2 _____
(Two decimals)

Why was data for T0 not obtained?

T1

Was any data obtained for T1? No
 Yes

Date and time _____
(DD-MM-YYYY HH:MM)

Name of ward Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

SpO2 _____
(%)

Type of oxygen delivery

None
 Nasal cannula
 Non-rebreather mask
 Intubated
 (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

Oxygen delivery

(L/min)

FiO2

(Two decimals)

Why was data for T1 not obtained?

T2

Was any data obtained for T2?

No
 Yes

Date and time

(DD-MM-YYYY HH:MM)

Name of ward

Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

SpO2

(%)

Type of oxygen delivery

None
 Nasal cannula
 Non-rebreather mask
 Intubated
 (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

 Oxygen delivery

 (L/min)

 FiO2

 (Two decimals)

 Why was data for T2 not obtained?

T3

 Was any data obtained for T3?

- No
 Yes

 Date and time

 (DD-MM-YYYY HH:MM)

 Name of ward

- Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

 SpO2

 (%)

 Type of oxygen delivery

- None
 Nasal cannula
 Non-rebreather mask
 Intubated
 (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

 Oxygen delivery

 (L/min)

 FiO2

 (Two decimals)

 Why was data for T3 not obtained?

T4

Was any data obtained for T4?

- No
 Yes

Date and time

(DD-MM-YYYY HH:MM)

Name of ward

- Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

SpO2

(%)

Type of oxygen delivery

- None
 Nasal cannula
 Non-rebreather mask
 Intubated
(If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

Oxygen delivery

(L/min)

FiO2

(Two decimals)

Why was data for T4 not obtained?

T5

Was any data obtained for T5?

- No
 Yes

Date and time

(DD-MM-YYYY HH:MM)

Name of ward

- Pre-hospital
- Trauma Centre
- Operating Room
- Examination Room
- Post-Anaesthesia Care Unit
- General Intensive Care Unit
- Neurointensive Care Unit
- Cardiothoracic Intensive Care Unit
- Normal ward

SpO2

(%)

Type of oxygen delivery

- None
 - Nasal cannula
 - Non-rebreather mask
 - Intubated
- (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

Oxygen delivery

(L/min)

FiO2

(Two decimals)

Why was data for T5 not obtained?

T6

Was any data obtained for T6?

- No
- Yes

Date and time

(DD-MM-YYYY HH:MM)

Name of ward

- Pre-hospital
- Trauma Centre
- Operating Room
- Examination Room
- Post-Anaesthesia Care Unit
- General Intensive Care Unit
- Neurointensive Care Unit
- Cardiothoracic Intensive Care Unit
- Normal ward

SpO2

(%)

Type of oxygen delivery

None
 Nasal cannula
 Non-rebreather mask
 Intubated
 (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

Oxygen delivery

(L/min)

FiO2

(Two decimals)

Why was data for T6 not obtained?

T7

Was any data obtained for T7?

No
 Yes

Date and time

(DD-MM-YYYY HH:MM)

Name of ward

Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

SpO2

(%)

Type of oxygen delivery

None
 Nasal cannula
 Non-rebreather mask
 Intubated
 (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

 Oxygen delivery

 (L/min)

 FiO2

 (Two decimals)

 Why was data for T7 not obtained?

T8

Was any data obtained for T8?

- No
 Yes

 Date and time

 (DD-MM-YYYY HH:MM)

 Name of ward

- Pre-hospital
 Trauma Centre
 Operating Room
 Examination Room
 Post-Anaesthesia Care Unit
 General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Normal ward

 SpO2

 (%)

 Type of oxygen delivery

- None
 Nasal cannula
 Non-rebreather mask
 Intubated
 (If this is unknown, mark it with the missing data code; both entry for oxygen delivery and FiO2 will appear. In case you have either the value for oxygen delivery or the FiO2, enter the value and mark the other (oxygen delivery/FiO2) with the missing data code)

 Oxygen delivery

 (L/min)

 FiO2

 (Two decimals)

 Why was data for T8 not obtained?

ARTERIAL BLOOD GAS (ABG) ANALYSES

1st ABG (at hour 1 ± 30 minutes (T1) after randomisation)PaO2

_____ (One decimal)

1st ABG (at hour 1 ± 30 minutes (T1) after randomisation)PaO2 unit

- Kilopascal (kPa)
 Millimetre of mercury (mmHg)

1st ABG (at hour 1 ± 30 minutes (T1) after randomisation)Date and time

_____ (DD-MM-YYYY HH:MM)

2nd ABG (at hour 6 ± 2 hours (T6) after randomisation)PaO2

_____ (One decimal)

2nd ABG (at hour 6 ± 2 hours (T6) after randomisation)PaO2 unit

- Kilopascal (kPa)
 Millimetre of mercury (mmHg)

2nd ABG (at hour 6 ± 2 hours (T6) after randomisation)Date and time

_____ (DD-MM-YYYY HH:MM)

PROTOCOL DEVIATIONS/VIOLATIONS AND COMMENTS

A major protocol violation is defined as:

Restrictive oxygen group: during the intervention period

- For non-intubated trial participants: Supplemental oxygen ≥ 3 L O₂/min and having an SpO₂ $\geq 98\%$ recorded in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"

- For intubated trial participants: FiO₂ ≥ 0.4 and having an SpO₂ $\geq 98\%$ recorded in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"

Liberal oxygen group: during the intervention period

- For non-intubated trial participants: Supplemental oxygen < 3 L O₂/min in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"

- For intubated trial participants: FiO₂ < 0.4 in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"

Did the treating physician deviate from the protocol at any point during the intervention?

- No
- Yes

Date and time of the protocol deviation

_____ (DD-MM-YYYY HH:MM)

What was the clinical justification behind the protocol deviation?

Were there any major protocol violations during the intervention?

- No
- Yes

When, how and why did the major protocol violation happen?

If you have any comments regarding the intervention, list them here

_____ (Lacking data points, missing ABGs etc.)

In-hospital patient data: Investigator

Record ID _____

TIME POINTS

Date and time of surgery initiation in the operating room

(DD-MM-YYYY HH:MM)

Date and time of surgery termination in the operating room

(DD-MM-YYYY HH:MM)

Duration of surgery (minutes)

(Number of minutes will appear after entering data on date and time of surgery initiation in the operating room and date and time of surgery termination in the operating room)

Where was the patient sent after undergoing surgery straight after the trauma centre?

- General Intensive Care Unit
 Neurointensive Care Unit
 Cardiothoracic Intensive Care Unit
 Ward

Date and time of arrival to the ward after undergoing surgery straight after the trauma centre

(DD-MM-YYYY HH:MM)

Date and time of arrival to the ward straight after the trauma centre

(DD-MM-YYYY HH:MM)

Was the patient admitted to an ICU at any point during initial admission at the ward?

- No
 Yes

Date and time of arrival to the ICU

(DD-MM-YYYY HH:MM; any kind of ICU (general ICU, neuro ICU or cardiothoracic ICU))

OTHER VARIABLES

Was brain injury present within 7 days during admission?

- No
 Yes

Specifics of brain injury (type and extent)

(Description based on the patient's medical record)

Did any of these protocol specified ischaemic events occur within 7 days during admission?

- Myocardial infarction
 Cerebral ischaemia
 None of the above

Date and time of the diagnosis myocardial infarction

(DD-MM-YYYY HH:MM)

Date and time of the diagnosis cerebral ischaemia

(DD-MM-YYYY HH:MM)

Adverse Event (AE) registration: Investigator

Record ID _____

INFORMATION

Adverse Event (AE): Any untoward medical occurrence in a subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment.

We only record the following AEs in this study:

- Atelectasis
- Irritability of airway mucosa

To monitor AEs, you must as a TRAUMOX2 investigator assess the patient's medical record:

- Once within the first 24 hours
- Every third day until discharge (maximum of 30 days)

ADVERSE EVENT DURING INTERVENTION

Do you want to register an AE that occurred during intervention?

- No
 Yes

Which AE occurred?

- Atelectasis
 Irritability of airway mucosa
(During intervention)

Date and time of the AE

(DD-MM-YYYY HH:MM; during intervention)

Description of the AE

(During intervention)

Assessment of the correlation between the AE and trial medicine

- 1: Unrelated - No temporal context; other etiologies are more likely to be the cause
 2: Possible related - Less clear connection; other etiologies are also possible
 3: Probably related - Clear temporal correlation with medication discontinuation, and not reasonably explained by the known clinical condition of the subject
 4: Related - Clear temporal relationship with rehabilitation test or clinical assessment
(During intervention)

ADVERSE EVENT DURING ADMISSION

Do you want to register an AE that occurred during admission?

- No
 Yes
(Up to a maximum of 30 days after trial intervention; after 30 days it is no longer needed to follow patients for AEs)

Which AE occurred?

- Atelectasis
 Irritability of airway mucosa
(During admission)

Date and time of the AE

(DD-MM-YYYY HH:MM; during admission)

Description of the AE

(During admission)

Assessment of the correlation between the AE and trial medicine

- 1: Unrelated - No temporal context; other etiologies are more likely to be the cause
 2: Possible related - Less clear connection; other etiologies are also possible
 3: Probably related - Clear temporal correlation with medication discontinuation, and not reasonably explained by the known clinical condition of the subject
 4: Related - Clear temporal relationship with rehabilitation test or clinical assessment
(During admission)

Serious Adverse Event (SAE) registration: Investigator and sponsor

Record ID _____

INFORMATION

Serious Adverse Event (SAE): Any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death.

To monitor SAEs, you must as a TRAUMOX2 investigator assess the patient's medical record:

- Once within the first 24 hours
- Every third day until discharge (maximum of 30 days)

Please read the TRAUMOX2 study protocol and "Registration of Serious Adverse Events in TRAUMOX2 v1.0 01-12-2021" for more details.

All SAEs registered and saved here in REDCap will immediately notify the sponsor and coordinating investigator via an automatic generated e-mail from the REDCap notification system.

[Attachment: "Registration of Serious Adverse Events in TRAUMOX2 v1.0 01-12-2021.pdf"]

SERIOUS ADVERSE EVENT REGISTRATION DURING INTERVENTION

INVESTIGATOR

Do you want to register an SAE that occurred during intervention?

- No
 Yes
(When clicking "Yes" and saving the record, the sponsor will immediately receive an e-mail notification)

To be filled in by INVESTIGATOR

Name of investigator _____

Type of SAE registration

- Initial registration
 Follow-up registration

Date and time of onset of the SAE during intervention

(DD-MM-YYYY HH:MM; when the SAE occurred for the patient)

Date and time of SAE investigator awareness

(DD-MM-YYYY HH:MM; when the SAE came to your awareness as an investigator)

Date and time of the SAE registration

(DD-MM-YYYY HH:MM (you may click "Now"))

SAE criteria

- Patient died
 - Was life-threatening
 - Involved or prolonged hospital length of stay
 - Involved persistence of significant disability or incapacity
 - Resulted in a congenital anomaly or birth defect
-

Date and time of death

(DD-MM-YYYY HH:MM)

Cause of death

SAE description

SAE diagnosis

Concomitant medication(s) relevant to the SAE (exclude those used to treat event)

Action taken on trial medicine

- No change
 - Drug dose changed
 - Drug temporarily discontinued
 - Drug permanently discontinued
-

Intervention starting date and time

(DD-MM-YYYY HH:MM; see date and time of randomisation in the data collection sheet)

Intervention changing/stopping date and time

(DD-MM-YYYY HH:MM)

Assessment by investigator of the correlation between the SAE and trial medicine

- 1: Unrelated - No temporal context; other etiologies are more likely to be the cause
 - 2: Possible related - Less clear connection; other etiologies are also possible
 - 3: Probably related - Clear temporal correlation with medication discontinuation, and not reasonably explained by the known clinical condition of the subject
 - 4: Related - Clear temporal relationship with rehabilitation test or clinical assessment
-

Was the patient discontinued from the study due to the SAE?

- No
 - Yes
-

Date and time of discontinuation

(DD-MM-YYYY HH:MM)

Date and time of the SAE end

(DD-MM-YYYY HH:MM)

To be filled in by SPONSOR

Date and time filled in by the sponsor to confirm that the SAE (during intervention) registration has been received

(DD-MM-YYYY HH:MM)

Signature by the sponsor to confirm that the SAE (during intervention) registration has been received

Assessment by sponsor of the correlation between the SAE and trial medicine

- 1: Unrelated - No temporal context; other etiologies are more likely to be the cause
- 2: Possible related - Less clear connection; other etiologies are also possible
- 3: Probably related - Clear temporal correlation with medication discontinuation, and not reasonably explained by the known clinical condition of the subject
- 4: Related - Clear temporal relationship with rehabilitation test or clinical assessment

Expectedness assessment by sponsor

- Expected
- Unexpected

Classification of the SAE after sponsor assessment

- SUSAR (SAE is both related and unexpected)
- SAR (SAE is related but not unexpected)
- SAE (SAE is not related and not unexpected)
- (Remember to notify relevant authorities if needed according to the protocol)

Sponsor's comments

Process of evaluation

- Ongoing
- Finished

Termination date of the SAE evaluation

(DD-MM-YYYY)

Signature by the sponsor to confirm termination of the SAE evaluation

SERIOUS ADVERSE EVENT REGISTRATION DURING/AFTER ADMISSION**INVESTIGATOR**

Do you want to register an SAE that occurred during/after admission?

- No
 Yes
 (When clicking "Yes" and saving the record, the sponsor will immediately receive an e-mail notification)

To be filled in by INVESTIGATOR

Name of investigator

Type of SAE registration

- Initial registration
 Follow-up registration

Date and time of onset of the SAE during/after admission

 (DD-MM-YYYY HH:MM; when the SAE occurred for the patient)

Date and time of SAE investigator awareness

 (DD-MM-YYYY HH:MM; when the SAE came to your awareness as an investigator)

Date and time of the SAE registration

 (DD-MM-YYYY HH:MM (you may click "Now"))

SAE criteria

- Patient died
 Was life-threatening
 Involved or prolonged hospital length of stay
 Involved persistence of significant disability or incapacity
 Resulted in a congenital anomaly or birth defect

Date and time of death

 (DD-MM-YYYY HH:MM)

Cause of death

SAE description

SAE diagnosis

Concomitant medication(s) relevant to the SAE (exclude those used to treat event)

Intervention starting date and time

(DD-MM-YYYY HH:MM; see date and time of randomisation in the data collection sheet)

Assessment by investigator of the correlation between the SAE and trial medicine

- 1: Unrelated - No temporal context; other etiologies are more likely to be the cause
- 2: Possible related - Less clear connection; other etiologies are also possible
- 3: Probably related - Clear temporal correlation with medication discontinuation, and not reasonably explained by the known clinical condition of the subject
- 4: Related - Clear temporal relationship with rehabilitation test or clinical assessment

Was the patient discontinued from the study due to the SAE?

- No
- Yes

Date and time of discontinuation

(DD-MM-YYYY HH:MM)

Date and time of the SAE end

(DD-MM-YYYY HH:MM)

To be filled in by SPONSOR

Date and time filled in by the sponsor to confirm that the SAE (during/after admission) registration has been received

(DD-MM-YYYY HH:MM)

Signature by the sponsor to confirm that the SAE (during/after admission) registration has been received

Assessment by sponsor of the correlation between the SAE and trial medicine

- 1: Unrelated - No temporal context; other etiologies are more likely to be the cause
- 2: Possible related - Less clear connection; other etiologies are also possible
- 3: Probably related - Clear temporal correlation with medication discontinuation, and not reasonably explained by the known clinical condition of the subject
- 4: Related - Clear temporal relationship with rehabilitation test or clinical assessment

Expectedness assessment by sponsor

- Expected
- Unexpected

Classification of the SAE after sponsor assessment

- SUSAR (SAE is both related and unexpected)
- SAR (SAE is related but not unexpected)
- SAE (SAE is not related and not unexpected)
(Remember to notify relevant authorities if needed according to the protocol)

Sponsor's comments

Process of evaluation

-
- Ongoing
 - Finished
-

Termination date of the SAE evaluation

(DD-MM-YYYY)

Signature by the sponsor to confirm termination of the SAE evaluation

Upload of consent form(s) for the biobank for future research: Investigator

Record ID _____

INVESTIGATOR

At the time of entering data on this patient, are you from a centre who participate in the biobank for future research?

- No
 Yes

Did the patient / patient's next-of-kin (on behalf of the patient) wish to participate in the biobank for future research?

- No
 Yes

Why did the patient / patient's next-of-kin (on behalf of the patient) not want to participate in the biobank for future research?

CONSENT FORM UPLOAD

Samtykkeerklæringer til biobanken for fremtidig forskning for danske centre kan findes i:

"File repository" (se menuen til venstre)

eller

Manuelt download af de udfyldte samtykkeerklæringer, som kan findes i toppen af de pågældende instruments ved klik på "Download PDF of instrument(s)"

eller

Hvis man undtagelsesvist har fået underskrift på papir, så scan det og upload her i REDCap

Who gave consent to let the patient participate in the biobank?

- Patient
 Patient's next-of-kin

Date of biobank consent: Patient

(DD-MM-YYYY)

Biobank consent form: Patient

Date of biobank proxy consent: Patient's next-of-kin

(DD-MM-YYYY)

Biobank proxy consent form: Patient's next-of-kin

IMPORTANT INFORMATION Additional data on the blood samples for the biobank for future research must be entered in another REDCap database established for this purpose

See the project bookmark in the left menu "REDCap: TRAUMOX2 biobank for future research"

Primary outcome: Investigator

Record ID

PRIMARY OUTCOME ASSESSMENT

Please see the attached document on how to assess the primary outcome

[Attachment: "Primary outcome assessment in TRAUMOX2 v1.0 25-11-2021.pdf"]

Please feel free to use this attached primary outcome tool document for the primary outcome assessment

[Attachment: "Primary outcome assessment tool TRAUMOX2 v1.0 24-02-2022.xlsx"]

Journal notes

Lab and microbiology results

Radiology description(s)

Name of primary outcome assessor 1

Name of primary outcome assessor 2

Occurrence of the combined primary outcome:

30-day mortality

AND / OR

Major lung complication(s) within 30 days

No

Yes

(Assessed by at least two treatment allocation blinded specialists in anaesthesia, intensive care, emergency medicine or similar)

Specify which outcome(s) occurred

Death

Pneumonia

ARDS

(It is possible to mark the occurrence of more than one outcome)

Mortality date

(DD-MM-YYYY)

Where can documentation be found?

(Regarding the circumstances of death)

Categorisation of pneumonia

Non-ventilator-associated pneumonia (PNEU)

Ventilator-associated pneumonia (VAP)

Date of confirmed pneumonia

(DD-MM-YYYY)

Where can documentation be found?

(Regarding the pneumonia assessment)

Categorisation of ARDS

- Mild
 Moderate
 Severe

Date of confirmed ARDS

(DD-MM-YYYY)

Where can documentation be found?

(Regarding the ARDS assessment)

Treatment allocation guess by primary outcome assessor
1

- Restrictive oxygen strategy
 Liberal oxygen strategy

Treatment allocation guess by primary outcome assessor
2

- Restrictive oxygen strategy
 Liberal oxygen strategy

If you have any comments regarding the primary outcome assessment, please list them here (from the primary outcome assessors or you as an investigator)

Secondary outcomes: Investigator

Record ID _____

SECONDARY OUTCOMES

Episode(s) of hypoxaemia during the 8 hours of intervention (saturation < 90%)

(From the data collection sheet; defined as number of times the valid oxygen saturation is below 90%; if it is below 90%, above 90% and below 90% again, then it should be registered as 2 episodes)

Was intubation performed in any of these settings?

- Pre-hospital
 Trauma Centre
 After being admitted to the hospital (post trauma centre treatment)
 The patient was never intubated during admission

Was the patient ventilated in the ICU?

- No
 Yes

Date and time of intubation

(DD-MM-YYYY HH:MM)

Was the patient extubated at any point during admission?

- No
 Yes

Date and time of extubation

(DD-MM-YYYY HH:MM)

Was the patient re-intubated at any point during admission?

- No
 Yes
(Only re-intubation in an ICU setting should be considered)

How many intubations (including the initial one) were performed within 30 days in total?

(Enter number of intubations; only intubations in an ICU setting should be considered)

Number of re-intubations

(Calculation based on total number of intubations minus 1 (total re-intubations); if the number 998 is shown here due to earlier entered missing data values (999), this value of 998 is similar to 999 (missing data value))

Date and time of ICU discharge

(DD-MM-YYYY HH:MM)

ICU LOS

(ICU LOS = Intensive Care Unit Length Of Stay; number of days will appear after data on date and time for admission to an ICU (located in the instrument "In-hospital patient data: Investigator") and date and time for discharge from an ICU (located in this instrument) are entered; calculation is set to round up equal day(s) with no decimals)

Was the patient re-admitted to an ICU at any point during admission?

- No
 Yes

How many days was the patient admitted to an ICU during the re-admission(s)?

(Enter manually the number of days for the re-admission(s) to an ICU besides the primary ICU admission; round up equal day(s) with no decimals)

Surgical site infection(s) within 30 days

At least one of the following:

- Purulent drainage
- Positive microbiologic testing from surgical site/wound
- Deliberately opened by a surgeon AND sign(s) of infection
- Diagnosis of surgical site infection by a surgeon

- No
 Yes
 (Defined as per the CDC criteria for a surgical site infection event)

Sepsis during hospital admission

- No
 Yes
 (Clearly stated in the patient's medical record by a physician or assigned as a diagnosis)

Pneumonia post-discharge within 30 days

- No
 Yes
 (Evaluated through medicines prescribed after hospital discharge in countries where this information is available; if the patient is still admitted after 30 days, enter "No")

Date and time of hospital discharge

- Only the primary admission should be considered (no re-admissions)

(DD-MM-YYYY HH:MM)

- If a patient is transferred from one hospital to another hospital for further treatment related to the trauma, it is not considered a hospital discharge

- If a patient is transferred from the hospital to a psychiatry department or a rehabilitation center for further treatment, then the day of transfer is considered the date of hospital discharge

Hospital LOS

(LOS = Length Of Stay; number of days will appear after data on date and time for arrival to the hospital (located in the instrument "Trauma centre patient data: Investigator") and date and time for discharge from the hospital (in this instrument) are entered; calculation is set to round up equal day(s) with no decimals)

Days alive outside the ICU

(Number of ICU-free days within 30 days after enrolment; round up day(s) with no decimals)

Time on mechanical ventilation

(Number of ventilator hours within 30 days after enrolment; only mechanical ventilation in the ICU should be considered; round up hour(s) with no decimals)

Days alive without mechanical ventilation

(Number of ventilator-free days within 30 days after enrolment; only mechanical ventilation in the ICU should be considered; round up day(s) with no decimals)

6- and 12-month follow-up (secondary outcomes): Investigator

Record ID

EQ-5D-5L

6 MONTHS POST-TRAUMA

Were you able to contact a respondent for the completion of the EQ-5D-5L questionnaire at 6 months post-trauma?

- No
 Yes

Why not?

Date of assessment

(DD-MM-YYYY)

Who was the respondent?

- Patient
 Patient's next-of-kin/friend/caretaker
 Patient + patient's next-of-kin/friend/caretaker

Mobility

(Enter the score from 1 to 5)

Self-care

(Enter the score from 1 to 5)

Usual activities

(Enter the score from 1 to 5)

Pain or discomfort

(Enter the score from 1 to 5)

Anxiety or depression

(Enter the score from 1 to 5)

EQ-5D VAS: The respondent's health today

(Enter the score from 0 to 100)

EQ-5D-5L: File upload

(6-month follow-up)

GOSE**6 MONTHS POST-TRAUMA**

Were you able to contact a respondent for the completion of the GOSE questionnaire at 6 months post-trauma?

- No
 Yes

Why not?

Date of assessment

 (DD-MM-YYYY)

Who was the respondent?

- Patient
 Patient's next-of-kin/friend/caretaker
 Patient + patient's next-of-kin/friend/caretaker

Since the structured interview for GOSE has a fairly high amount of questions, we wish that you, the investigator, uploads the completed interview document and enters the final GOSE score here in REDCap

1	Death
2	Vegetative state
3	Lower severe disability
4	Upper severe disability
5	Lower moderate disability
6	Upper moderate disability
7	Lower good recovery
8	Upper good recovery

GOSE score

 (Enter the score from 1 to 8)

GOSE: File upload

(6-month follow-up)

MORTALITY**12 MONTHS POST-TRAUMA**

Was information available on mortality status at 12 months post-trauma?

- No
 Yes

Why not?

12-month mortality

- No
 Yes

Date of death

(DD-MM-YYYY)

EQ-5D-5L**12 MONTHS POST-TRAUMA**

Were you able to contact a respondent for the completion of the EQ-5D-5L questionnaire at 12 months post-trauma?

- No
 Yes

Why not?

Date of assessment

Who was the respondent?

- Patient
 Patient's next-of-kin/friend/caretaker
 Patient + patient's next-of-kin/friend/caretaker

Mobility

(Enter the score from 1 to 5)

Self-care

(Enter the score from 1 to 5)

Usual activities

(Enter the score from 1 to 5)

Pain or discomfort

(Enter the score from 1 to 5)

Anxiety or depression

(Enter the score from 1 to 5)

EQ-5D VAS: The respondent's health today

(Enter the score from 0 to 100)

EQ-5D-5L: File upload

(12-month follow-up)

GOSE**12 MONTHS POST-TRAUMA**

Were you able to contact a respondent for the completion of the GOSE questionnaire at 12 months post-trauma?

- No
 Yes

Why not?

Date of assessment

(DD-MM-YYYY)

Who was the respondent?

- Patient
 Patient's next-of-kin/friend/caretaker
 Patient + patient's next-of-kin/friend/caretaker

Since the structured interview for GOSE has a fairly high amount of questions, we wish that you, the investigator, uploads the completed interview document and enters the final GOSE score here in REDCap

1	Death
2	Vegetative state
3	Lower severe disability
4	Upper severe disability
5	Lower moderate disability
6	Upper moderate disability
7	Lower good recovery
8	Upper good recovery

GOSE score

(Enter the score from 1 to 8)

GOSE: File upload

(12-month follow-up)