

# Screening and patient inclusion details

To the including physician / healthcare professional 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 NOT 8J4JR4W7T THE STUDY ID IS FOUND IN THE RANDOMISATION BOX)

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
- Eligible for other EMC study

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 Akutlægeheliokopter  
 Billund Akutlægeheliokopter  
 Skive Akutlægeheliokopter  
 Nord Akutlægeheliokopter  
 ALB Odense  
 ALB Aarhus  
 ALB Silkeborg  
 ALB Horsens  
 ALB Randers  
 HEMS and physician car, Rotterdam, The Netherlands  
 BRN Rega 3  
 BRN Rega 10  
 BRN Rega 14  
 BRN SanPol

To which trauma centre?

- Rigshospitalet, Copenhagen, Denmark  
 Odense Universitetshospital, Odense, Denmark  
 Aarhus Universitetshospital, Aarhus, Denmark  
 Erasmus Medical Center, Rotterdam, The Netherlands  
 University Hospital Bern, Switzerland

Which trauma centre?

- Rigshospitalet, Copenhagen, Denmark  
 Odense Universitetshospital, Odense, Denmark  
 Aarhus Universitetshospital, Aarhus, Denmark  
 University Hospital of Cologne, Cologne, Germany  
 Erasmus Medical Center, Rotterdam, The Netherlands  
 University Hospital Bern, Switzerland

Airway at inclusion?

- Non-intubated  
 Intubated

Randomisation group?

- Restrictive oxygen strategy  
 Liberal oxygen strategy

**PATIENT INFORMATION**

Danish CPR/replacement CPR?

- No  
 Yes  
 (For sites outside of Denmark, always enter "No")

Patient name / Study acronym

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

Sex

- Male  
 Female

Patient's date/year of birth known?

- No  
 Yes

Date of birth

\_\_\_\_\_  
(DD-MM-YYYY)

Year of birth

\_\_\_\_\_  
(If date of birth is not allowed to be entered)

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 / HEALTHCARE PROFESSIONAL**

Name of the including physician / healthcare professional

\_\_\_\_\_

Signature by the including physician / healthcare professional

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

\_\_\_\_\_

# Upload of consent forms: Investigator

Record ID

\_\_\_\_\_

## CONSENT FORMS

Status on the consent proces with the next-of-kin or the patient

(You may use this box for regular updates on the consent proces with the next-of-kin or the patient)

Date of consent: Next-of-kin

\_\_\_\_\_

Proxy consent: Next-of-kin

(Only if the patient is not able to give informed consent. Leave it blank if you are not allowed to upload consent forms.)

Date of consent: Patient

\_\_\_\_\_

Informed consent: Patient

( Leave it blank if you are not allowed to upload consent forms.)

Status on acceptance for 6- and 12 month follow-up

- Acceptance of follow-up at 6- and 12 months  
 No acceptance of follow-up at 6- and 12 months

Any comments on consent and/or follow-up

\_\_\_\_\_

## WITHDRAWAL OF CONSENT

Did the next-of-kin or the patient withdraw consent at any point?

- No  
 Yes

Who withdrew consent?

- Next-of-kin  
 Patient

Date of consent withdrawal: Next-of-kin

\_\_\_\_\_  
(DD-MM-YYYY)

Date of consent withdrawal: Patient

\_\_\_\_\_  
(DD-MM-YYYY)

# Patient characteristics and history after inclusion: Investigator

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Record ID

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## CHARACTERISTICS AND DEMOGRAPHICS

---

Patient name

---

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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)?

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(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)

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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)

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Indication for supplemental oxygen treatment before randomisation

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

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Supplementary oxygen administration form before randomisation

- Nasal cannula
- Non-rebreather mask
- Intubated

---

Initial oxygen flow chosen

\_\_\_\_\_

(L/min)

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Initial FiO2 chosen

\_\_\_\_\_

(Two decimals)

# Trauma centre patient data: Investigator

Record ID

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## 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)

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(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
- Eligible for other EMC study

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)

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AIS: Face

\_\_\_\_\_ (AIS score)

---

AIS: Thorax / Thoracic spine

\_\_\_\_\_ (AIS score)

---

AIS: Abdomen / Lumbar spine

\_\_\_\_\_ (AIS score)

---

AIS: Extremity

\_\_\_\_\_ (AIS score)

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AIS: External incl. skin injuries and burns

\_\_\_\_\_ (AIS score)

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Injury Severity Score (ISS)

\_\_\_\_\_ (ISS calculation based on AIS scores)

# Data collection sheet: Investigator

Record ID \_\_\_\_\_

**From the 7th of March, 2022, a version 1.1 of the data collection sheet is used**

**If your study site has received randomisation envelopes before this date, you have the version 1.0**

**Therefore, multiple terms are used here in REDCap to cover both the version 1.0 and version 1.1**

Example of the data collection sheet version 1.0

[Attachment: "Example of the data collection sheet v1.0.pdf"]

Example of the data collection sheet version 1.1

[Attachment: "Example of the data collection sheet v1.1.pdf"]

## 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) / Before randomisation**

Was any data obtained for T0 / Before randomisation?

- No  
 Yes

Date and time

\_\_\_\_\_  
(DD-MM-YYYY HH:MM)

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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 / Oxygen flow

\_\_\_\_\_  
(L/min)

FiO2

\_\_\_\_\_  
(Two decimals)

Why was data for T0 / Before randomisation not obtained?

\_\_\_\_\_

**T1 / Hour 1**

Was any data obtained for T1 / Hour 1?

- No  
 Yes

Date and time

\_\_\_\_\_  
(DD-MM-YYYY HH:MM)



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Name of ward / Location

- 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 / Type of supplemental oxygen

- 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)

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Oxygen delivery / Oxygen flow

\_\_\_\_\_

(L/min)

---

FiO2

\_\_\_\_\_

(Two decimals)

---

Why was data for T1 / Hour 1 not obtained?

\_\_\_\_\_

---

**T2 / Hour 2**

Was any data obtained for T2 / Hour 2?

- No
- Yes

---

Date and time

\_\_\_\_\_

(DD-MM-YYYY HH:MM)

---

Name of ward / Location

- 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

\_\_\_\_\_

(%)

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Type of oxygen delivery / Type of supplemental oxygen

- 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 / Oxygen flow

\_\_\_\_\_  
(L/min)

FiO2

\_\_\_\_\_  
(Two decimals)

Why was data for T2 / Hour 2 not obtained?

\_\_\_\_\_

**T3 / Hour 3**

Was any data obtained for T3 / Hour 3?

- No
- Yes

Date and time

\_\_\_\_\_  
(DD-MM-YYYY HH:MM)

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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 / Oxygen flow

\_\_\_\_\_

(L/min)

---

FiO2

\_\_\_\_\_

(Two decimals)

---

Why was data for T3 / Hour 3 not obtained?

\_\_\_\_\_

#### **T4 / Hour 4**

Was any data obtained for T4 / Hour 4?

- No  
 Yes
- 

Date and time

\_\_\_\_\_

(DD-MM-YYYY HH:MM)

---

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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 / Oxygen flow

\_\_\_\_\_

(L/min)

---

FiO2

\_\_\_\_\_

(Two decimals)

---

Why was data for T4 / Hour 4 not obtained?

\_\_\_\_\_

**T5 / Hour 5**

Was any data obtained for T5 / Hour 5?

- No  
 Yes

Date and time

---

 (DD-MM-YYYY HH:MM)

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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 / Oxygen flow

---

 (L/min)

FiO2

---

 (Two decimals)

Why was data for T5 / Hour 5 not obtained?

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**T6 / Hour 6**

Was any data obtained for T6 / Hour 6?

- No  
 Yes

Date and time

---

 (DD-MM-YYYY HH:MM)

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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 / Oxygen flow

\_\_\_\_\_

(L/min)

FiO2

\_\_\_\_\_

(Two decimals)

Why was data for T6 / Hour 6 not obtained?

\_\_\_\_\_

**T7 / Hour 7**

Was any data obtained for T7 / Hour 7?

- No
- Yes

Date and time

\_\_\_\_\_

(DD-MM-YYYY HH:MM)

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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 / Oxygen flow

\_\_\_\_\_  
(L/min)

FiO2

\_\_\_\_\_  
(Two decimals)

Why was data for T7 / Hour 7 not obtained?

\_\_\_\_\_

### T8 / Hour 8

Was any data obtained for T8 / Hour 8?

- No  
 Yes

Date and time

\_\_\_\_\_  
(DD-MM-YYYY HH:MM)

Name of ward / Location

- 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 / Type of supplemental oxygen

- 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)

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Oxygen delivery / Oxygen flow

\_\_\_\_\_

(L/min)

---

FiO<sub>2</sub>

\_\_\_\_\_

(Two decimals)

---

Why was data for T8 / Hour 8 not obtained?

\_\_\_\_\_

### ARTERIAL BLOOD GAS (ABG) ANALYSES

1st ABG (at hour 1 ± 30 minutes (T1) after randomisation)PaO<sub>2</sub>

\_\_\_\_\_

(One decimal)

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1st ABG (at hour 1 ± 30 minutes (T1) after randomisation)PaO<sub>2</sub> 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)PaO<sub>2</sub>

\_\_\_\_\_

(One decimal)

---

2nd ABG (at hour 6 ± 2 hours (T6) after randomisation)PaO<sub>2</sub> 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)

### ADDITIONAL DATA FROM THE ARTERIAL BLOOD GASSES

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

\_\_\_\_\_

(One decimal)

---

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

- mmol/L  
 g/dL
- 

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

\_\_\_\_\_

(mmol/L; one decimal)

---

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

\_\_\_\_\_

(One decimal)

---

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

- mmol/L  
 g/dL

2nd ABG (at hour  $6 \pm 2$  hours (T6) after randomisation)Lactate

(mmol/L; one decimal)

## 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  $\geq 3$  L O<sub>2</sub>/min and having an SpO<sub>2</sub>  $\geq 98\%$  recorded in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"**

**- For intubated trial participants: FiO<sub>2</sub>  $> 0.4$  and having an SpO<sub>2</sub>  $\geq 98\%$  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 O<sub>2</sub>/min in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"**

**- For intubated trial participants: FiO<sub>2</sub>  $< 0.4$  in two consecutive hourly values in the data collection sheet: "Randomisation, data collection sheet and REDCap inclusion"**

**Data from T0 / Before randomisation should not be considered as part of the two consecutive hourly values in the assessment of a major protocol violation**

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 ishcaemia

\_\_\_\_\_  
(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 (only atelectases assessed by a radiologist are recorded)
- Irritability of airway mucosa (recorded only if registered by the health care staff in the medical record)

Only the first AE of either atelectasis or irritability of airway mucosa should be recorded during intervention/admission (not a subsequent)

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 v1.1 24-05-2022" 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 v1.1 24-05-2022.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

---

# 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 v1.2 06-10-2022.pdf"]

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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"]

---

Medical record

---

Lab and microbiology results

---

Radiology description(s)

---

Name of primary outcome assessor 1

---

---

Name of primary outcome assessor 2

---

---

30-day mortality

- No  
 Yes

---

Mortality date

---

(DD-MM-YYYY)

---

Where can documentation be found?

---

(Regarding the circumstances of death)

---

Pneumonia within 30 days from inclusion

- No  
 Yes

---

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)

---

ARDS within 30 days from inclusion

- No
- Yes

---

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%)

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; only intubation pre-hospital, in the trauma centre and in the ICU should be considered; in case a patient remains intubated in the ICU following intubation in the operating room, the date and time for intubation should be the arrival time in the ICU)

Was the patient extubated at any point during admission?

- No  
 Yes

Date and time of extubation defined as:

1) Date and time when endotracheal tube is removed without the need for a tracheostomy tube (if the time is not exactly specified, then the best approximation)

2) If the patient has a tracheostomy:

- Date when the tracheostomy tube is removed

- Date when a cuffed tracheostomy tube is replaced with a non-cuffed tube

The following is not considered as date of extubation while having a tracheostomy:

1) If the patient sometimes has a cuffed tube and sometimes has a non-cuffed tube (e.g., switches between day-time and night-time)

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 pre-hospital, in the trauma centre and in the ICU 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 commenced 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 Enter commenced 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 after enrolment

- No  
 Yes  
 Patient is still admitted 30 days after enrolment (Evaluated through medicines prescribed after hospital discharge in countries where this information is available)

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 commenced day(s) with no decimals)

Days alive outside the ICU

(Number of ICU-free days within 30 days after enrolment Commenced day(s) with no decimals (e.g., 1 hour of ICU admission = 1 ICU day = 29 days alive outside the ICU))

Time on mechanical ventilation

Defined as:

1) Positive pressure ventilation at any time, including Bilevel Positive Airway Pressure (BiPAP)

The following treatments are not considered as mechanical ventilation:

1) Non-invasive ventilation (NIV), high flow nasal cannula or Continuous Positive Airway Pressure (CPAP)

Endotracheal intubation and mechanical ventilation during surgery is not included in the above definitions if the patient is breathing spontaneously without an endotracheal tube before surgery

(Number of ventilator hours within 30 days after enrolment; only mechanical ventilation started pre-hospital, in the trauma centre or in the ICU should be considered Commenced hour(s) with no decimals (e.g., 1 hour and 15 minutes on mechanical ventilation = 2 hours on mechanical ventilation))



---

Days alive without mechanical ventilation

(Number of ventilator-free days within 30 days after enrolment; only mechanical ventilation started pre-hospital, in the trauma centre or in the ICU should be considered Commenced day(s) with no decimals (e.g., 1 hour on mechanical ventilation = 1 day = 29 days alive without mechanical ventilation))

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

Record ID \_\_\_\_\_

## 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
- Dead

Why not?

- No answer despite several attempts
- Missing contact information
- Patient did not wish to participate in follow-up
- Other (describe in box below)

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)

Har personen med en hjerneskade siden traumet haft nogle epileptiske anfald?

- Nej  
 Ja

GOSE: File upload

(6-month follow-up)

### 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  
 Dead

Why not?

- No answer despite several attempts  
 Missing contact information  
 Patient did not wish to participate in follow-up  
 Other (describe in box below)

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)

**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)

**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
- Dead

Why not?

- No answer despite several attempts
- Missing contact information
- Patient did not wish to participate in follow-up
- Other (describe in box below)

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)

Har personen med en hjerneskade siden traumet haft nogle epileptiske anfald?

- Nej  
 Ja

GOSE: File upload

\_\_\_\_\_  
(12-month follow-up)

### 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  
 Dead

Why not?

- No answer despite several attempts  
 Missing contact information  
 Patient did not wish to participate in follow-up  
 Other (describe in box below)

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)

# Study completion information: Investigator

Record ID

---

## STUDY COMPLETION TIME POINTS

Did the patient or patient's next of kin not give consent/withdrew consent from the study at any point?

- No  
 Yes

Who did not give consent/withdrew consent on behalf of the patient?

- Patient  
 Patient's next-of-kin

Date of consent withdrawal: Patient

\_\_\_\_\_  
(DD-MM-YYYY)

Date of consent withdrawal: Patient's next-of-kin

\_\_\_\_\_  
(DD-MM-YYYY)

Was the patient excluded from the study at any point by an investigator?

- No  
 Yes

Describe when and why the patient was excluded

\_\_\_\_\_

Date of exclusion

\_\_\_\_\_  
(DD-MM-YYYY)

Did the patient complete the 8-hour intervention?

- No  
 Yes  
(If "No" is chosen, the explanation should be given in the "Data collection sheet" instrument)

Did the patient complete the 30-day follow up?

- No  
 Yes

Explain why 30-day follow-up was not possible

\_\_\_\_\_

Did the patient complete the 6-month follow-up?

- No  
 Yes

Explain why 6-month follow-up was not possible

\_\_\_\_\_

Did the patient complete the 12-month follow-up?

- No  
 Yes

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Explain why 12-month follow-up was not possible

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Any general comments?

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(If none, leave the box blank)

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Date of final overall assessment

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(DD-MM-YYYY: The final overall study assessment of the patient)

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Name of the terminating investigator

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(Must be a physician)

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Signature by the terminating investigator

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(Must be a physician)