Screening and patient inclusion details

To the including physician / healthcare professionalPlease 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 ≥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 8J4JR4W7TTHE 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 Akutlægehelikopter
- ◯ Billund Akutlægehelikopter
- ◯ Skive Akutlægehelikopter
- ◯ Nord Akutlægehelikopter
- ◯ 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

_____

Kontaktoplysninger på 1. forsøgsværge: Investigator

INVESTIGATOR UDFYLDER NEDENSTÅENDE

Navn: 1. forsøgsværge

_____

Hvordan indhentes det forudgående stedfortrædende samtykke fra 1. forsøgsværge?

◯ Gennem e-mail link
◯ Åbnes direkte i REDCap og udfyldes
◯ Udfyldes på papir og uploades i REDCap

E-mail: 1. forsøgsværge

_____

(Når e-mail udfyldes og gemmes, så sendes samtykkeerklæringen automatisk til 1. forsøgsværge)

Forudgående stedfortrædende samtykke: 1. forsøgsværge

Forudgående stedfortrædende samtykkeerklæring (1. forsøgsværge) til akut lægemiddelforsøg

Forskningsprojektets titel:

Comparing Restrictive vs. Liberal Oxygen Strategies for Trauma Patients: The TRAUMOX2 Trial

Videnskabetisk Komité journal-nr.: H-21018062
EudraCT nummer: 2021-000556-19

Version 1.0

Erklæring fra forsøgsværgen (en uafhængig læge): Jeg erklærer hermed, at jeg har fået skriftlig information om det konkrete forskningsprojekt samt oplysning om forsøgspersonens tilstand. Jeg er uafhængig af den forsøgsansvarliges interesser og af interesser i forskningsprojektet i øvrigt og giver - som varetager af forsøgspersonens interesser - samtykke til, at forsøgspersonen deltager i forskningsprojektet.

Forsøgspersonens navn

_____
(Hvis navnet er ukendt, så skriv "ukendt")

Kender du patientens CPR-nummer?

◯ Nej
◯ Ja
(Hvis der klikkes "Nej", vil det være muligt at skrive et erstatnings CPR-nummer)

Erstatnings CPR-nummer

_____
(Erstatnings CPR-nummer uden bindestreg)

CPR-nummer

_____
(CPR-nummer uden bindestreg)

Navnet på forsøgsværgen

_____

Dato

_____
(DD-MM-YYYY; datoen for hvornår samtykket er afgivet i forbindelse med inklusion)

Underskrift

_____

Erklæring fra den, der afgiver information: Jeg erklærer, at forsøgsværgen har fået skriftlig information om det konkrete forskningsprojekt samt oplysning om forsøgspersonens tilstand.

Navnet på den, der har afgivet information

_____

Dato

_____

(DD-MM-YYYY; datoen for hvornår samtykket er afgivet i forbindelse med inklusion)

Underskrift

_____

Underskrift

Kontaktoplysninger på 2. forsøgsværge: Investigator

INVESTIGATOR UDFYLDER NEDENSTÅENDE

Navn: 2. forsøgsværge

_____

Hvordan indhentes det efterfølgende stedfortrædende samtykke fra 2. forsøgsværge?

◯ Gennem e-mail link
◯ Åbnes direkte i REDCap og udfyldes
◯ Udfyldes på papir og uploades i REDCap

E-mail: 2. forsøgsværge

_____

(Når e-mail udfyldes og gemmes, så sendes samtykkeerklæringen automatisk til 2. forsøgsværge)

Efterfølgende stedfortrædende samtykke: 2. forsøgsværge

Efterfølgende stedfortrædende samtykkeerklæring (2. forsøgsværge) til akut lægemiddelforsøg

Forskningsprojektets titel:

Comparing Restrictive vs. Liberal Oxygen Strategies for Trauma Patients: The TRAUMOX2 Trial

Videnskabetisk Komité journal-nr.: H-21018062
EudraCT nummer: 2021-000556-19

Version 1.0

Erklæring fra forsøgsværgen (en uafhængig læge): Jeg erklærer hermed, at jeg har fået skriftlig information om det konkrete forskningsprojekt samt oplysning om forsøgspersonens tilstand. Jeg er uafhængig af den forsøgsansvarliges interesser og af interesser i forskningsprojektet i øvrigt og giver - som varetager af forsøgspersonens interesser - samtykke til, at forsøgspersonen deltager i forskningsprojektet.

Forsøgspersonens navn

_____

Kender du patientens CPR-nummer?

◯ Nej
◯ Ja
(Hvis der klikkes "Nej", vil det være muligt at skrive et erstatnings CPR-nummer)

Erstatnings CPR-nummer

_____
(Erstatnings CPR-nummer uden bindestreg)

CPR-nummer

_____
(CPR-nummer uden bindestreg)

Navnet på forsøgsværgen

_____

Dato

_____
(DD-MM-YYYY; dags dato for afgivelse af samtykket)

Underskrift

_____

Erklæring fra den, der afgiver information: Jeg erklærer, at forsøgsværgen har fået skriftlig information om det konkrete forskningsprojekt samt oplysning om forsøgspersonens tilstand.

Navnet på den, der har afgivet information

_____

Dato

_____
(DD-MM-YYYY)

Underskrift

_____

Stedfortrædende samtykke: Pårørende

Stedfortrædende samtykke (pårørende) til deltagelse i et sundhedsvidenskabeligt forskningsprojekt

Forskningsprojektets titel:

Comparing Restrictive vs. Liberal Oxygen Strategies for Trauma Patients: The TRAUMOX2 Trial

Videnskabetisk Komité journal-nr.: H-21018062
EudraCT nummer: 2021-000556-19
Version 1.1

Erklæring fra den person, som afgiver stedfortrædende samtykke:Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at give mit samtykke.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at forsøgspersonen mister sine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til, at forsøgspersonen deltager i forskningsprojektet. Jeg har fået en kopi af den skriftlige information om projektet til eget brug. Jeg er også blevet tilbudt en kopi af dette samtykkeark til eget brug, hvis jeg ønsker sådan en.

56) Forsøgspersonens navn _____

57) Oplysning om min tilknytning, som pårørende, til forsøgspersonen _____

58) Navnet på den person, der giver stedfortrædende samtykke _____

59) Ønskes information om forskningsprojektets resultat samt eventuelle konsekvenser for forsøgspersonen?
◯ Nej
◯ Ja

60) Dato _____
(DD-MM-YYYY)

61) Underskrift _____

Erklæring fra den, der afgiver information:Jeg erklærer, at der er afgivet mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om forsøgspersonens deltagelse i forsøget.

62) Navnet på den, der har afgivet information _____

63) Dato

_____
(DD-MM-YYYY)

64) Underskrift

_____

Informeret samtykke: Patient

Informeret samtykke (forsøgsperson) til deltagelse i et sundhedsvidenskabeligt forskningsprojekt

Forskningsprojektets titel:

Comparing Restrictive vs. Liberal Oxygen Strategies for Trauma Patients: The TRAUMOX2 Trial

Videnskabetisk Komité journal-nr.: H-21018062
EudraCT nummer: 2021-000556-19
Version 1.1

Erklæring fra forsøgspersonen:Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til at deltage i forskningsprojektet. Jeg har fået en kopi af den skriftlige information om projektet til eget brug. Jeg er også blevet tilbudt en kopi af dette samtykkeark til eget brug, hvis jeg ønsker sådan en.

65) Forsøgspersonens navn

_____

66) Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?
◯ Nej
◯ Ja

67) Dato

_____
(DD-MM-YYYY)

68) Underskrift

_____

Erklæring fra den, der afgiver information:Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

69) Navnet på den, der har afgivet information

_____

70) Dato

_____
(DD-MM-YYYY)

71) Underskrift

_____

Upload af danske samtykkeerklæringer: Investigator

Samtykkeerklæringer kan findes i:

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, læg det i fysisk TMF og upload her i REDCap

Forudgående stedfortrædende samtykke: 1. forsøgsværge	
Kommentarer til indhentning af forudgående stedfortrædende samtykke: 1. forsøgsværge	_____ (Opdater løbende undervejs mhp. status for indhentelse)
Efterfølgende stedfortrædende samtykke: 2. forsøgsværge	
Kommentarer til indhentning af efterfølgende stedfortrædende samtykke: 2. forsøgsværge	_____ (Opdater løbende undervejs mhp. status for indhentelse)
Er det nødvendigt med stedfortrædende samtykke fra pårørende grundet patientens manglende evne til selv at kunne give samtykke?	◯ Nej ◯ Ja
Har det været muligt at komme i kontakt med de(n) pårørende mhp. indhentning af samtykke?	◯ Nej ◯ Ja
Har pårørende ønsket at give samtykke?	◯ Nej ◯ Ja
Stedfortrædende samtykke: Pårørende	
Kan patienten selv give samtykke?	◯ Nej ◯ Ja
Har det været muligt at komme i kontakt med patienten mhp. indhentning af samtykke?	◯ Nej ◯ Ja
Har patienten ønsket at give samtykke?	◯ Nej ◯ Ja
Informeret samtykke: Patient	

Status på indhentning af samtykke fra pårørende/patient?	_____ (Opdater gerne denne boks løbende!Kunne patient/pårørende ikke kontaktes; angiv dato og tidspunkt for informationssamtale; afventer man stadig svar; er der evt. noget særligt der er blevet informeret om; er samtykke indhentet mm.)
Efter endelig afklaring om samtykke, er det så blevet journalført?	◯ Nej ◯ Ja ◯ Ikke nødvendigt
Årsag til manglende ønske om at give samtykke fra pårørende/patient	_____
Pårørende eller patienten har givet samtykke til at deltage i studiet, og har givet følgende tilsagn om 6- og 12 måneders follow-up	◯ Vil fortsat gerne kontaktes ved 6- og 12 måneders follow-up ◯ Frabeder sig at blive kontaktet både ved 6- og 12 måneders follow-up ◯ Vil gerne kontaktes efter 6 måneder, men frabeder sig at blive kontaktet efter 12 måneder ◯ Vil gerne kontaktes efter 12 måneder, men frabeder sig at blive kontaktet efter 6 måneder (Hvis det er endt med, at der både foreligger samtykke fra pårørende og patienten, så er det patientens tilsagn, der skal være udfyldt)
Eventuelle kommentarer til samtykke og follow-up	_____

VED EVENTUEL TILBAGETRÆKNING AF SAMTYKKE

Har pårørende eller patienten trukket sit samtykke tilbage?	◯ Nej ◯ Ja
Hvem trak samtykket tilbage?	◯ Pårørende ◯ Patienten
Dato for tilbagetrækning af samtykke: Pårørende	_____
Dato for tilbagetrækning af samtykke: Patient	_____

Upload of consent forms: Investigator

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

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

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

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 randomisaton 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)

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

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)

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 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	_____ (%)

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?
_____

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)

Oxygen delivery / Oxygen flow

_____
(L/min)

FiO2

_____
(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)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)

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 ± 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 ≥3 L O2/min and having an SpO2 ≥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 ≥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"

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

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 initation 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

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

INFORMATION

Serious Adverse Event (SAE): Any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of exisiting 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 receieve 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 receieve 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	_____

Stedfortrædende samtykke til biobank til fremtidig forskning: Pårørende

Stedfortrædende samtykke
(pårørende)med henblik på deltagelse i en biobank til fremtidig forskning via deltagelse i TRAUMOX2 studiet

Erklæring fra den person, som afgiver stedfortrædende samtykke:Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage og give samtykke på vegne af min pårørende.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at min pårørende som forsøgsperson mister sine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til at lade min pårørende deltage i biobanken. Jeg er blevet tilbudt muligheden for at få udleveret en kopi af den skriftlige deltagerinformation og samtykkeark til eget brug.

364) Forsøgspersonens navn

_____

365) Oplysning om min tilknytning, som pårørende, til forsøgspersonen

_____

366) Navnet på den person, der giver stedfortrædende samtykke

_____

367) Dato

_____
(DD-MM-YYYY)

368) Underskrift

_____

Erklæring fra den, der afgiver information:Jeg erklærer, at pårørende til forsøgspersonen har modtaget mundtlig og skriftlig information om biobanken.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i biobanken.

369) Navnet på den, der har afgivet information

_____

370) Dato

_____
(DD-MM-YYYY)

371) Underskrift

_____

Informeret samtykke til biobank til fremtidig forskning: Patient

Informeret samtykke
(forsøgsperson)med henblik på deltagelse i en biobank til fremtidig forskning via deltagelse i TRAUMOX2 studiet

Erklæring fra forsøgspersonen:Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til at deltage i biobanken. Jeg er blevet tilbudt muligheden for at få udleveret en kopi af den skriftlige deltagerinformation og samtykkeark til eget brug.

372) Forsøgspersonens navn

_____

373) Dato

_____
(DD-MM-YYYY)

374) Underskrift

_____

Erklæring fra den, der afgiver information:Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om biobanken.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i biobanken.

375) Navnet på den, der har afgivet information

_____

376) Dato

_____
(DD-MM-YYYY)

377) Underskrift

_____

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

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 INFORMATIONAdditional 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"

Dansk journalmateriale

Notater
Radiologi
Biokemi
Biokemi2
Biokemi3
Biokemi4
Mikrobio

Stedfortrædende samtykke biomarkør: Pårørende

Stedfortrædende samtykke (pårørende) til deltagelse i et sundhedsvidenskabeligt forskningsprojekt

Forskningsprojektets titel:

Biomarkers of oxidative stress in trauma patients receiving a liberal of restrictive oxygen strategy: A study on TRAUMOX2 patients

Videnskabetisk Komité journal-nr.: H-21018062
EudraCT nummer: 2021-000556-19
Version 1.0
Appendix 18: Særskilt samtykkeerklæring til pårørende i TRAUMOX2 delforsøg

Erklæring fra den person, som afgiver stedfortrædende samtykke:Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at give mit samtykke.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at forsøgspersonen mister sine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til, at forsøgspersonen deltager i forskningsprojektet og til at forsøgspersonens biologiske materiale udtages med henblik på opbevaring i en forskningsbiobank. Jeg har fået en kopi af den skriftlige information om projektet til eget brug. Jeg er også blevet tilbudt en kopi af dette samtykkeark til eget brug, hvis jeg ønsker sådan en.

393) Forsøgspersonens navn _____

394) Oplysning om min tilknytning, som pårørende, til forsøgspersonen _____

395) Navnet på den person, der giver stedfortrædende samtykke _____

396) Ønskes information om forskningsprojektets resultat samt eventuelle konsekvenser for forsøgspersonen?
◯ Nej
◯ Ja

397) Dato _____ (DD-MM-YYYY)

398) Underskrift _____

Erklæring fra den, der afgiver information:Jeg erklærer, at der er afgivet mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om forsøgspersonens deltagelse i forsøget.

399) Navnet på den, der har afgivet information

_____

400) Dato

_____
(DD-MM-YYYY)

401) Underskrift

_____

Informeret samtykke biomarkør: Patient

Informeret samtykke (forsøgsperson) til deltagelse i et sundhedsvidenskabeligt forskningsprojekt

Forskningsprojektets titel:

Biomarkers of oxidative stress in trauma patients receiving a liberal or restrictive oxygen strategy: A study on TRAUMOX2 patients

Videnskabetisk Komité journal-nr.: H-21018062
EudraCT nummer: 2021-000556-19
Version 1.0
Appendix 16: Særskilt samtykkeerklæring til forsøgsperson i TRAUMOX2 delforsøg

Erklæring fra forsøgspersonen:Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til at deltage i forskningsprojektet og til at mit biologiske materiale udtages med henblik på obevaring i en forskningsbiobank. Jeg har fået en kopi af den skriftlige information om projektet til eget brug. Jeg er også blevet tilbudt en kopi af dette samtykkeark til eget brug, hvis jeg ønsker sådan en.

402) Forsøgspersonens navn _____

403) Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?
◯ Nej
◯ Ja

404) Dato _____ (DD-MM-YYYY)

405) Underskrift _____

Erklæring fra den, der afgiver information:Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

406) Navnet på den, der har afgivet information _____

407) Dato _____ (DD-MM-YYYY)

408) Underskrift

_____

Biomarkør: Investigator

INKLUSION

Er patienten inkluderet i biomarkør studiet?	◯ Nej ◯ Ja
Årsag til at patienten ikke er inkluderet Inkluderet [scr_incl_date_incl] [sheet_rand_time]	◯ Ankommet uden for inklusions tidsvindue ◯ Ekskluderet fra TRAUMOX2 inden blodprøve blev taget i TC (FAILINCL og SECEX) ◯ Misset inklusion ◯ Andet (skriv kommentar nedenunder) (Inklusions tidsvindue er som udgangspunkt kl. 06.00-14.30 fra mandag til fredag)
Evt. kommentarer til at patienten ikke er inkluderet	_____

EKSKLUSION EFTER INKLUSION

Er patienten blevet ekskluderet fra biomarkør studiet efter inklusion? Man skal blot opfylde ét af tre eksklusionskriterier: 1. Ekskluderet fra TRAUMOX2 Herunder både FAILINCL og SECEX 2. Udskrivelse inden for 24 timer Udskrevet, overflyttet til andet hospital eller død inden for 24 timer 3. Protokolovertrædelse i TRAUMOX2 Se "Data collection sheet: Investigator" instrumentet for at se, om der er sket en protokolovertrædelse	◯ Nej ◯ Ja
Hvilket eksklusionskriterie?	◯ Ekskluderet fra TRAUMOX2 ◯ Udskrivelse inden for 24 timer ◯ Protokolovertrædelse i TRAUMOX2
Dato for eksklusion fra biomarkør studiet	_____
Er KBA orienteret om aflysning af PTB og blodbanken om destruktion af prøver?	◯ Nej ◯ Ja (Skriv ind i vores excel-ark ved eksklusion eller NOCONS og prøver skal destrueres! Tryk altid bare NejKontakt Andreas Brix Bjaaland (mail: andreas.brix.bjaaland@regionh.dk) fra KBA om PTB aflysningKontakt Betina Poulsen (mail: betina.poulsen@regionh.dk) fra blodbanken om destruktion af prøver)

BLODPRØVETAGNINGER

Tidspunkt for initiering af TRAUMOX2 intervention: [scr_incl_date_incl] [sheet_rand_time]

Tidspunkt for H0 blodprøvetagning

_____
(H0 blodprøven tages af bioanalytiker i TC fra Klinisk Biokemisk Afdeling 3011 (vi kan/må til nøds også godt), når patienten er inkluderet i TRAUMOX2 Tidspunkt kan findes under "Laboratoriesvar" i SP under blodprøvesvaret for LABKA koden "RGH00869")

Hvordan er H0 blodprøven taget?

◯ Veneblod uden pågående infusion
◯ A-kanyle
◯ CVK med pågående infusion

Tidspunkt for H8 blodprøvetagning
Intervention slut: [sheet_term_study_interve]

_____
(HUSK at H8 blodprøven tages, når TRAUMOX2 intervention er afsluttet og op til 2 timer efter endt intervention)

Hvordan er H8 blodprøven taget?

◯ Veneblod uden pågående infusion
◯ A-kanyle
◯ CVK med pågående infusion

Tidspunkt for H24 blodprøvetagning

_____
(Blodprøve tages 24 timer ± 3 timer efter initiering af TRAUMOX2 intervention)

Hvordan er H24 blodprøven taget?

◯ Veneblod uden pågående infusion
◯ A-kanyle
◯ CVK med pågående infusion

Tidspunkt for H48 blodprøvetagning

_____
(Blodprøve tages 48 timer ± 3 timer efter initiering af TRAUMOX2 intervention)

Hvordan er H48 blodprøven taget?

◯ Veneblod uden pågående infusion
◯ A-kanyle
◯ CVK med pågående infusion

Evt. kommentarer til blodprøvetagninger

_____
(Kommenter specifikt på den enkelte blodprøvetagning (H0, H8, H24 eller H48) hvis kommentar er nødvendig)

SAMTYKKE

Stedfortrædende samtykke biomarkør: Pårørende	(Uploades kun hvis nødvendigt)
Informeret samtykke biomarkør: Patient	
Status på indhentning af samtykke fra pårørende/patient?	_____ (Opdater gerne denne boks løbende!Kunne patient/pårørende ikke kontaktes; angiv dato og tidspunkt for informationssamtale; afventer man stadig svar; er der evt. noget særligt der er blevet informeret om; er samtykke indhentet mm.)
Samtykke status	◯ Givet samtykke til både forskningsbiobank og biobank til fremtidig forskning ◯ Givet samtykke kun til forskningsbiobank ◯ Ønsker ikke at give samtykke ◯ Patient er endeligt inkluderet på baggrund af 1. værge og/eller 2. værge samtykke (Hvis der foreligger samtykke fra både pårørende og patient, så er det patientens tilsagn, der skal være udfyldt. Hvis patienten ikke ønsker at samtykke, så HUSK at kontakt Andreas/Betina angående PTB aflysning og prøvedestruktion! Hak felt højere oppe af.)
Må allerede indsamlede prøver beholdes?	◯ Nej ◯ Ja (Hvis der svares Nej, så skal alle indsamlede prøver destrueresHvis der svares Ja, så må man beholde alle prøver, der allerede er indsamlet)
Dato for nej til samtykke	_____
Evt. kommentarer til samtykke	_____

VED EVENTUEL TILBAGETRÆKNING AF SAMTYKKE

Har pårørende eller patient trukket sit samtykke tilbage?	◯ Nej ◯ Ja (OBS! Husk aflysning af PTB og destruktion af prøver, hvis samtykke trækkes tilbage (se felt højere oppe i dette instrument, hvis dette felt markeres med "Ja"))
Hvem trak samtykket tilbage?	◯ Pårørende ◯ Patienten
Dato for tilbagetrækning af samtykke: Pårørende	_____
Dato for tilbagetrækning af samtykke: Patient	_____

Primary outcome: Investigator

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"]

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

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? 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)	◯ 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 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 enteredCalculation 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 admissionEnter 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) - If a patient is transfered from one hospital to another hospital for further treatment related to the trauma, it is not considered a hospital discharge - If a patient is transfered 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	_____ (DD-MM-YYYY HH:MM)
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 enteredCalculation is set to commenced day(s) with no decimals)
Days alive outside the ICU	_____ (Number of ICU-free days within 30 days after enrolmentCommenced 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 consideredCommenced 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

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 wih 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

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
Explain why 12-month follow-up was not possible	_____

Any general comments?

_____
(If none, leave the box blank)

Date of final overall assessment

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

Name of the terminating investigator

_____
(Must be a physician)

Signature by the terminating investigator

_____
(Must be a physician)