Randomisation - Eligibility

ProMISe

Time of presentation at ED

Presentation at ED: Today (1) Yesterday (2) Time: H H : M M (24-hour clock)

Inclusion

Met once, in any order, within six hours from presentation at ED

Known or presumed infection: Yes (Y)

Two, or more SIRS criteria: Yes (Y)

Refractory hypotension or hypoperfusion: Yes (Y)

You now have two hours to consent and randomise the patient

Exclusion

Transferred from another in-hospital setting: No (N)

Requirement for immediate surgery: No (N)

Age less than 18 years: No (N)

Do-Not-Attempt-Resuscitation (DNAR) status: No (N)

Advanced directives restricting implementation of the protocol: No (N)

Attending physician deems aggressive care unsuitable: No (N)

Contraindication to central venous catheterisation: No (N)

Contraindication to blood transfusion: No (N)

Known history of AIDS: No (N)

Primary diagnosis of; an acute cerebral vascular event, acute coronary syndrome, acute pulmonary oedema, status asthmaticus, major cardiac arrhythmia (as part of primary diagnosis), seizure, drug overdose, injury from burn or trauma: No (N)

Haemodynamic instability due to active gastrointestinal haemorrhage: No (N)

Known pregnancy: No (N)

Not able to complete six hours of protocol treatment from commencement: No (N)

Not able to commence protocol within one hour of randomisation: No (N)

N.B. If during screening, a patient is found to be participating in another interventional study/trial, then please contact the ICNARC CTU on 020 7269 9295 to discuss their participation in ProMISe

Treatment limitations

Does the patient have any other treatment limitations? *(see: overleaf for guidance)* Yes (Y) No (N)

Not requested in call to Randomisation Service

If yes, please specify

Time met physiological inclusion criteria

Time met final physiological inclusion criteria: H H : M M (24-hour clock)

Consent

Consent process used: Patient consent (1) Personal Consultee (2) Professional Consultee (3) Emergency consent (4)

Antimicrobial(s)

Antimicrobial(s) initiated: Yes (Y)

Randomisation

Trial number: Treatment allocation: Early, goal-directed, protocolised resuscitation (E) Usual resuscitation (U)

Randomisation (T_0) Date: D D / M M / 2 0 Y Y Time: H H : M M (24-hour clock)

First "golden" hour (T_1) Date: D D / M M / 2 0 Y Y Time: H H : 0 0 (24-hour clock)

Completed by: **Signature:**

promise@icnarc.org

Randomisation – Eligibility

Overleaf, to be completed once consent/agreement is obtained and before calling the Randomisation Service

Time of presentation at ED

- Presentation at ED – day the patient physically presented at ED
- Time – time the patient physically presented at ED

Inclusion

All should be ticked 'Yes' to be eligible

- Two, or more SIRS criteria

SIRS criteria		**Results**
Core temperature	≤ 36°C or ≥ 38°C	
Heart rate	≥ 90 beats min^{-1}	
Respiratory rate	≥ 20 breaths min^{-1}	
or Hyperventilaton	$PaCO_2$ < 4.3 kPa **or** mechanical ventilation for acute process	
White blood cell count	≤ $4x10^9$ l^{-1} **or** ≥ $12×10^9$ l^{-1}	
or Immature neutrophils (bands)	> 10%	

- Refractory hypotension or hypoperfusion

Physiology		**Results**
Refractory hypotension	MAP < 65 mmHg **or** SBP < 90 mmHg	
or Hypoperfusion	blood lactate ≥ 4 mmol l^{-1}	

Exclusion

All should be ticked 'No' to be eligible

Treatment limitations

- Does the patient have any other treatment limitations? – these are treatment limitations which do not prevent delivery of the early, goal-directed, protocolised resuscitation (obviously, ones that do, exclude the patient from ProMISe), e.g.
  - a patient whose treatment limitation precludes the use of inotropic agents would be excluded from ProMISe
  - a patient whose treatment limitation precludes the use of mechanical ventilation would be eligible for ProMISe, because the early, goal-directed, protocolised resuscitation requires that mechanical ventilation only be considered

Consent

- Consent process used –
  - Patient consent – the patient provided informed consent
  - Personal Consultee – a relative or friend provided agreement
  - Professional Consultee – an Independent Mental Capacity Advocate provided agreement
  - Emergency consent – an independent doctor was consulted and agreed

Antimicrobial(s)

- Antimicrobial(s) initiated – first dose must be initiated before randomisation

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Randomisation

Randomisation Service – 020 8099 7784
Study number – 2016
Investigator number – XXX

- Trial number – provided by the Randomisation Service
- Treatment allocation – provided by the Randomisation Service
- Randomisation (T_0) – complete date and time provided by the Randomisation Service
- First "golden" hour (T_1) – date and time provided by the Randomisation Service

ProMISe

icnarc intensive care national audit & research centre

Protocolised Management In Sepsis

A multi-centre, randomised controlled trial
of the clinical and cost-effectiveness of
early, goal-directed, protocolised resuscitation
for emerging septic shock

Case Report Form

Investigator number

Trial number

Treatment allocation

Early, goal-directed, protocolised resuscitation (E)

Usual resuscitation (U)

Randomisation (T_0)

Date: D D / M M / 2 0 Y Y Time: H H : M M

T_1

Date: D D / M M / 2 0 Y Y Time: H H : 0 0

ProMISe

Trial number: | | | | |

Randomisation - Inclusion criteria

(results confirming inclusion criteria)

Inclusion criteria

Blood pressure (after fluid challenge) - MAP: | | | mmHg **or** SBP: | | | mmHg

Lactate: | | . | | mmol l^{-1}

Known or presumed infection: Yes (Y) No (N)

Temperature: | | . | | °C

Heart rate: | | | beats min^{-1}

Respiratory rate: | | | breaths min^{-1}

$PaCO_2$: | | | . | | kPa (K) mmHg (M)

Mechanical ventilation: Yes (Y) No (N)

White blood count: | | | . | | 10^9 l^{-1}

Immature neutrophils (bandforms): | | %

For SIRS criteria

First dose of IV antimicrobial(s) initiated: Yes (Y) No (N)

IV antimicrobial(s) initiated:

Care location

Would patient be admitted direct to ICU from ED if not enrolled into ProMISe? Yes (Y) No (N)

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

Baseline - Contact details

ProMISe

Trial number: | | | | |

Patient details

Title:

First name:

Surname:

Gender: Male (M) Female (F)

Date of birth: D D / M M / 1 9 Y Y

or Estimated age:

NHS number:

Hospital number:

House number/name:

Postcode:

Address 1:

Address 2:

City:

County:

Country:

If address not known

Residence/status: Abroad (A) Military (M) Homeless (H) No fixed abode (N)

Telephone number:

Mobile number:

Other number:

Primary care details

Initials:

Surname:

Practice name:

House number/name:

Postcode:

Address 1:

Address 2:

City:

County:

Country:

Clinician details

Treating clinician responsible for patient

Title:

First name:

Surname:

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

Baseline - Physiology/Interventions

(last result prior to randomisation)

ProMISe

Trial number: ☐☐☐☐

Physiology

Not recorded (NR)

Temperature: ☐☐·☐ °C NR

MAP: ☐☐☐ mmHg **or** NR

SBP/DBP: ☐☐☐/☐☐☐ mmHg

Heart rate: ☐☐☐ beats min^{-1} NR

Respiratory rate: ☐☐☐ breaths min^{-1} NR

Mechanical ventilation: Yes (Y) No (N)

FiO_2: ☐·☐☐ NR

PaO_2: ☐☐☐·☐ kPa (K) mmHg (M) NR

$PaCO_2$: ☐☐☐·☐ kPa (K) mmHg (M) NR

Arterial pH: ☐·☐☐ NR

CVP: ☐☐ mmHg NR

SpO_2: ☐☐☐ % NR

$ScvO_2$: ☐☐☐ % NR

Not recorded (NR)

Sodium: ☐☐☐ mmol l^{-1} NR

Potassium: ☐☐·☐ mmol l^{-1} NR

Lactate: ☐☐·☐ mmol l^{-1} NR

Creatinine: ☐☐☐☐ µmol l^{-1} NR

Bilirubin: ☐☐☐·☐ µmol l^{-1} NR

Platelets: ☐☐☐☐ x10^9 l^{-1} NR

Haemoglobin: ☐☐·☐ g dl^{-1} NR

White blood count: ☐☐☐·☐ x10^9 l^{-1} NR

Immature neutrophils (bandforms): ☐☐ % NR

Glasgow Coma Score (GCS)

Pre-sedation: Yes (Y) No (N)

Not recorded: (NR)

Total GCS: ☐☐

Eye opening response

- Spontaneous: 4
- To speech: 3
- To painful stimuli: 2
- No response: 1

Motor response

- Obeys commands: 6
- Localises to painful stimuli: 5
- Withdrawal to painful stimuli: 4
- Abnormal flexion: 3
- Extends to painful stimuli: 2
- No response: 1

Verbal response

- Oriented: 5
- Confused: 4
- Inappropriate words: 3
- Incomprehensible sounds: 2
- No response: 1

Interventions

Vasoactives administered: Yes (Y) No (N)

If yes

Dobutamine: Yes (Y)

Dopamine: Yes (Y) Rate →

- ≤5 µg kg^{-1} min^{-1} (L)
- >5 µg kg^{-1} min^{-1} (M)
- >15 µg kg^{-1} min^{-1} (U)

Epinephrine: Yes (Y) Rate →

- ≤0.1 µg kg^{-1} min^{-1} (L)
- >0.1 µg kg^{-1} min^{-1} (U)

Norepinephrine: Yes (Y) Rate →

- ≤0.1 µg kg^{-1} min^{-1} (L)
- >0.1 µg kg^{-1} min^{-1} (U)

IV fluid (total volume)

Pre-hospital: ☐☐☐☐☐ ml → ED presentation to randomisation: ☐☐☐☐☐ ml

Blood products (total volume)

Pre-hospital: ☐☐☐☐ ml → ED presentation to randomisation: ☐☐☐☐ ml

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

ProMISe

Trial number: | | | | |

Baseline - Comorbidities

(last six months prior to ED presentation)

Comorbidities

Does the patient have any of the listed comorbidities? Yes (Y) No (N)

If yes

Liver

Cirrhosis: (Y)

Portal hypertension: (Y)

Upper GI bleeding (due to portal hypertension): (Y)

Hepatic failure or encephalopathy: (Y)

Haematological/oncological

AIDS: (Y)

Lymphoma: (Y)

Leukaemia: (Y)

Myeloma: (Y)

Metastatic disease: (Y)

Renal

Chronic renal replacement therapy for irreversible renal disease: (Y)
(haemodialysis, haemofiltration and peritoneal dialysis)

Respiratory

Shortness of breath with light activity: (Y)

Home ventilation: (Y)

Cardiovascular

Fatigue, claudication, dyspnoea or angina at rest: (Y)
(New York Heart Association Functional Class IV)

Neurological

Altered mental state: (Y)

Immunological

Therapy supressing resistance to infection: (Y)
(e.g. steroids, chemotherapy, radiotherapy, etc.)

Other

Admitted from a Nursing Home: (Y)

Other: (Y)

Specify other:

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

ProMISe

Trial number: | | | | |

Resuscitation - Lines

Lines

CVC with $ScvO_2$ monitoring capability: Yes (Y) No (N) PreSep catheter batch number: | | | | | | | | |

If yes

Date of insertion: D D / M M / 2 0 Y Y

Time of insertion: H H : M M (24-hour clock)

CVC without $ScvO_2$ monitoring capability: Yes (Y) No (N)

If yes

Date of insertion: D D / M M / 2 0 Y Y

Time of insertion: H H : M M (24-hour clock)

Arterial line: Yes (Y) No (N)

If yes

Date of insertion: D D / M M / 2 0 Y Y

Time of insertion: H H : M M (24-hour clock)

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

ProMISe

Resuscitation - T0 → T1

T1*: H H : 0 0 (24-hour clock)

Trial number: ____

Interventions T0 → T1*

Supplemental O_2: Yes (Y) → ____ l min^{-1} No (N)

Highest FiO_2: ____ . ____

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ____ ml

Crystalloid: Yes (Y) → ____ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Other: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Specify other: ____

PRBC: Yes (Y) → ____ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ____ ml

FFP: Yes (Y) → ____ ml

Albumin (20%): Yes (Y) → ____ ml

Other: Yes (Y) → ____ ml

Specify other: ____

Max. infusion rate

Dobutamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: ____

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T1*

Not recorded (NR)

CVP: ____ mmHg (NR)

MAP: ____ mmHg (NR)

SBP: ____ mmHg (NR)

Not recorded (NR)

$ScvO_2$: ____ % (NR)

Haemoglobin: ____ . ____ g dl^{-1} (NR)

*T1

T0 = time of randomisation and T1 = time of randomisation plus one "golden" hour
e.g. patient randomised at 18:25, T1 = 20:00, patient randomised at 19:04, T1 = 21:00

Completed by: ____

Signature: ____ **Date completed:** D D / M M / 2 0 Y Y

ProMISe

Resuscitation – T1 → T2

T2: H H : 0 0 (24-hour clock)

Trial number: ____

Interventions T1 → T2

Supplemental O_2: Yes (Y) → ____ l min^{-1} No (N)

Highest FiO_2: ____ . ____

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ____ ml

Crystalloid: Yes (Y) → ____ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Other: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Specify other: ____

PRBC: Yes (Y) → ____ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ____ ml

FFP: Yes (Y) → ____ ml

Albumin (20%): Yes (Y) → ____ ml

Other: Yes (Y) → ____ ml

Specify other: ____

Max. infusion rate

Dobutamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: ____

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T2

Not recorded (NR)

CVP: ____ mmHg (NR)

MAP: ____ mmHg (NR)

SBP: ____ mmHg (NR)

Not recorded (NR)

$ScvO_2$: ____ % (NR)

Haemoglobin: ____ . ____ g dl^{-1} (NR)

Comments

Completed by: ____

Signature: ____

Date completed: D D / M M / 2 0 Y Y

Resuscitation – T2 → T3

T3: H H : 0 0 (24-hour clock)

Trial number:

Interventions T2 → T3

Supplemental O_2: Yes (Y) → l min^{-1} No (N)

Highest FiO_2: . %

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ml

Crystalloid: Yes (Y) → ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → . µg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → . µg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → . µg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → . µg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → . µg kg^{-1} min^{-1}

Other: Yes (Y) → . µg kg^{-1} min^{-1}

Specify other:

PRBC: Yes (Y) → ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ml

FFP: Yes (Y) → ml

Albumin (20%): Yes (Y) → ml

Other: Yes (Y) → ml

Specify other:

Max. infusion rate

Dobutamine: Yes (Y) → . µg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other:

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T3

Not recorded (NR)

CVP: mmHg (NR)

MAP: mmHg (NR)

SBP: mmHg (NR)

Not recorded (NR)

$ScvO_2$: % (NR)

Haemoglobin: . g dl^{-1} (NR)

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

Resuscitation – T3 → T4

T4: H H : 0 0 (24-hour clock)

Trial number: ☐☐☐☐

Interventions T3 → T4

Supplemental O_2: Yes (Y) → ☐☐ l min^{-1} No (N)

Highest FiO_2: ☐ . ☐☐

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ☐☐☐☐ ml

Crystalloid: Yes (Y) → ☐☐☐☐☐ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → ☐ . ☐ μg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → ☐ . ☐☐ μg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → ☐ . ☐☐ μg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1}

Other: Yes (Y) → ☐☐ . ☐☐ μg kg^{-1} min^{-1}

Specify other: ☐

PRBC: Yes (Y) → ☐☐☐☐ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ☐☐☐ ml

FFP: Yes (Y) → ☐☐☐☐ ml

Albumin (20%): Yes (Y) → ☐☐☐☐ ml

Other: Yes (Y) → ☐☐☐☐ ml

Specify other: ☐

Max. infusion rate

Dobutamine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: ☐

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T4

Not recorded (NR)

CVP: ☐☐ mmHg (NR)

MAP: ☐☐☐ mmHg (NR)

SBP: ☐☐☐ mmHg (NR)

Not recorded (NR)

$ScvO_2$: ☐☐☐ % (NR)

Haemoglobin: ☐☐ . ☐ g dl^{-1} (NR)

Comments

Completed by: ☐

Signature: ☐ **Date completed:** D D / M M / 2 0 Y Y

ProMISe

Resuscitation – T4 → T5

T5: H H : 0 0 (24-hour clock)

Trial number: _____

Interventions T4 → T5

Supplemental O_2: Yes (Y) → _____ l min^{-1} No (N)

Highest FiO_2: _____ . _____

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → _____ ml

Crystalloid: Yes (Y) → _____ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → _____ . _____ µg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → _____ . _____ µg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → _____ . _____ µg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → _____ . _____ µg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → _____ . _____ µg kg^{-1} min^{-1}

Other: Yes (Y) → _____ . _____ µg kg^{-1} min^{-1}

Specify other: _____

PRBC: Yes (Y) → _____ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → _____ ml

FFP: Yes (Y) → _____ ml

Albumin (20%): Yes (Y) → _____ ml

Other: Yes (Y) → _____ ml

Specify other: _____

Max. infusion rate

Dobutamine: Yes (Y) → _____ . _____ µg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: _____

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T5

Not recorded (NR)

CVP: _____ mmHg (NR)

MAP: _____ mmHg (NR)

SBP: _____ mmHg (NR)

Not recorded (NR)

$ScvO_2$: _____ % (NR)

Haemoglobin: _____ . _____ g dl^{-1} (NR)

Comments

Completed by: _____

Signature: _____

Date completed: D D / M M / 2 0 Y Y

ProMISe

Resuscitation – T5 → T6

T6: H H : 0 0 (24-hour clock)

Trial number: ____

Interventions T5 → T6

Supplemental O_2: Yes (Y) → ____ l min^{-1} No (N)

Highest FiO_2: ____ . ____

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ____ ml

Crystalloid: Yes (Y) → ____ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Other: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1}

Specify other: ____

PRBC: Yes (Y) → ____ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ____ ml

FFP: Yes (Y) → ____ ml

Albumin (20%): Yes (Y) → ____ ml

Other: Yes (Y) → ____ ml

Specify other: ____

Max. infusion rate

Dobutamine: Yes (Y) → ____ . ____ µg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: ____

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T6

Not recorded (NR)

CVP: ____ mmHg (NR)

MAP: ____ mmHg (NR)

SBP: ____ mmHg (NR)

Not recorded (NR)

$ScvO_2$: ____ % (NR)

Haemoglobin: ____ . ____ g dl^{-1} (NR)

Lactate: ____ . ____ mmol l^{-1} (NR)

Comments

Completed by: ____

Signature: ____

Date completed: D D / M M / 2 0 Y Y

PROMISE

Trial number: | | | | |

Resuscitation – T0 → T6

Doctor T0 → T6

Most senior doctor to review patient (T0® T6):

- Foundation Year 1/2 (F)
- Specialty Registrar (year 1 – 7) (R)
- Consultant (C)
- Clinical Fellow (L)
- Staff or Associate Specialist (S)
- Other (O)

Specify:

Speciality of most senior doctor:

- Emergency Medicine (E)
- Intensive Care Medicine (I)
- Acute Medicine (A)
- Surgery (S)
- Other (O)

Specify:

Physiology T0 → T6

Lowest P/F ratio:

Not recorded (NR)

PaO_2: | | | | . | | kPa (K) mmHg (M) (NR)

FiO_2: | | . | |

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Not recorded (NR)

Lowest platelets: | | | | | $x10^9 l^{-1}$ (NR)

Highest bilirubin: | | | . | | µmol l^{-1} (NR)

Highest creatinine: | | | | µmol l^{-1} (NR)

Glasgow Coma Score (GCS) T0 → T6

Pre-sedation: Yes (Y) No (N)

Not recorded: (NR)

Lowest total GCS: | |

Eye opening response

- Spontaneous: 4
- To speech: 3
- To painful stimuli: 2
- No response: 1

Motor response

- Obeys commands: 6
- Localises to painful stimuli: 5
- Withdrawal to painful stimuli: 4
- Abnormal flexion: 3
- Extends to painful stimuli: 2
- No response: 1

Verbal response

- Oriented: 5
- Confused: 4
- Inappropriate words: 3
- Incomprehensible sounds: 2
- No response: 1

End of resuscitation protocol

End of early, goal-directed, protocolised resuscitation (if randomised to)

Date: D D / M M / 2 0 Y Y Time: H H : M M (24-hour clock)

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

ProMISe

Trial number: ☐☐☐☐

T6 → T24 - Interventions

T24

Date: D D / M M / 2 0 Y Y Time: H H : 0 0 (24-hour clock)

Interventions T6 → T24

Supplemental O_2: Yes (Y) → ☐☐ l min^{-1} No (N)

Highest FiO_2: ☐ . ☐☐

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ☐☐☐☐ ml

Crystalloid: Yes (Y) → ☐☐☐☐☐ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → ☐ . ☐ μg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → ☐ . ☐☐ μg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → ☐ . ☐☐ μg kg^{-1} min^{-1}

Phenylephrine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1}

Other: Yes (Y) → ☐☐ . ☐☐ μg kg^{-1} min^{-1}

Specify other: ☐

PRBC: Yes (Y) → ☐☐☐☐ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ☐☐☐ ml

FFP: Yes (Y) → ☐☐☐☐ ml

Albumin (20%): Yes (Y) → ☐☐☐☐ ml

Other: Yes (Y) → ☐☐☐☐ ml

Specify other: ☐

Max. infusion rate

Dobutamine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: ☐

Neuromuscular blocking agent: Yes (Y) No (N)

Comments

Completed by: ☐

Signature: ☐ **Date completed:** D D / M M / 2 0 Y Y

T6 → T24 - Physiology

PROMISE
Trial number:

Physiology T6 → T24

Lowest P/F ratio:

Not recorded (NR)

PaO_2: ___ . ___ kPa (K) mmHg (M) (NR)

FiO_2: ___ . ___

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ___ mmHg **or**

Lowest SBP/DBP: ___ / ___ mmHg (NR)

Not recorded (NR)

Lowest platelets: ___ $x10^9 l^{-1}$ (NR)

Highest bilirubin: ___ . ___ µmol l^{-1} (NR)

Highest creatinine: ___ µmol l^{-1} (NR)

Glasgow Coma Score (GCS) T6 → T24

Pre-sedation: Yes (Y) No (N)

Not recorded: (NR)

Lowest total GCS: ___

Eye opening response

- Spontaneous: 4
- To speech: 3
- To painful stimuli: 2
- No response: 1

Motor response

- Obeys commands: 6
- Localises to painful stimuli: 5
- Withdrawal to painful stimuli: 4
- Abnormal flexion: 3
- Extends to painful stimuli: 2
- No response: 1

Verbal response

- Oriented: 5
- Confused: 4
- Inappropriate words: 3
- Incomprehensible sounds: 2
- No response: 1

Physiology at T24

Not recorded (NR)

Lactate: ___ . ___ mmol l^{-1} (NR)

Not recorded (NR)

Haemoglobin: ___ . ___ g dl^{-1} (NR)

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

ProMISe

Trial number: ☐☐☐☐

T24 → T72 – Interventions/Physiology

T72

Date: D D / M M / 2 0 Y Y Time: H H : 0 0 (24-hour clock)

Interventions T24 → T72

Supplemental O_2: Yes (Y) → ☐☐ l min^{-1} No (N)

Highest FiO_2: ☐ . ☐☐

Mechanical ventilation: Yes (Y) No (N)

IV fluid(s): Yes (Y) No (N)

If yes

Colloid: (exclude blood products) Yes (Y) → ☐☐☐☐ ml

Crystalloid: Yes (Y) → ☐☐☐☐☐ ml

Vasoactive agents: Yes (Y) No (N)

If yes

Max. infusion rate

Dopamine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1}

Dopexamine: Yes (Y) → ☐ . ☐ μg kg^{-1} min^{-1}

Epinephrine: Yes (Y) → ☐ . ☐☐ μg kg^{-1} min^{-1}

Norepinephrine Yes (Y) → ☐ . ☐☐ μg kg^{-1} min^{-1}

Phenylephrine Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1}

Other: Yes (Y) → ☐☐ . ☐☐ μg kg^{-1} min^{-1}

Specify other: ☐

PRBC: Yes (Y) → ☐☐☐☐ ml No (N)

Other blood products: Yes (Y) No (N)

If yes

Platelets: Yes (Y) → ☐☐☐ ml

FFP: Yes (Y) → ☐☐☐☐ ml

Albumin (20%): Yes (Y) → ☐☐☐☐ ml

Other: Yes (Y) → ☐☐☐☐ ml

Specify other: ☐

Max. infusion rate

Dobutamine: Yes (Y) → ☐☐ . ☐ μg kg^{-1} min^{-1} No (N)

Sedated: Yes (Y) No (N)

If yes

Sedative(s): Benzodiazepine: (B) Propofol: (P) Opioid: (D) Other: (O)

Specify other: ☐

Neuromuscular blocking agent: Yes (Y) No (N)

Physiology at T72

Lactate: ☐☐ . ☐ mmol l^{-1} (NR) — Not recorded (NR)

Haemoglobin: ☐☐ . ☐ g dl^{-1} (NR) — Not recorded (NR)

Completed by: ☐

Signature: ☐ **Date completed:** D D / M M / 2 0 Y Y

T48 → T72 – Interventions/Physiology/Infection

ProMISe
Trial number: ☐☐☐☐

Interventions T48 →T72

Vasoactives administered: Yes (Y) No (N)

If yes

Dobutamine: Yes (Y)

Dopamine: Yes (Y) Max. rate →
- ≤5 µg kg^{-1} min^{-1} (L)
- >5 µg kg^{-1} min^{-1} (M)
- >15 µg kg^{-1} min^{-1} (U)

Epinephrine: Yes (Y) Max. rate →
- ≤0.1 µg kg^{-1} min^{-1} (L)
- >0.1 µg kg^{-1} min^{-1} (U)

Norepinephrine: Yes (Y) Max. rate →
- ≤0.1 µg kg^{-1} min^{-1} (L)
- >0.1 µg kg^{-1} min^{-1} (U)

Physiology T48 → T72

Lowest P/F ratio: Not recorded (NR)

PaO_2: ☐☐☐.☐ kPa (K) mmHg (M) (NR)

FiO_2: ☐.☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or**

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg (NR)

Not recorded (NR)

Lowest platelets: ☐☐☐☐ x10^9 l^{-1} (NR)

Highest bilirubin: ☐☐☐.☐ µmol l^{-1} (NR)

Highest creatinine: ☐☐☐☐ µmol l^{-1} (NR)

Glasgow Coma Score (GCS) T48 →T72

Pre-sedation: Yes (Y) No (N)

Not recorded: (NR)

Lowest total GCS: ☐☐

Eye opening response
- Spontaneous: 4
- To speech: 3
- To painful stimuli: 2
- No response: 1

Motor response
- Obeys commands: 6
- Localises to painful stimuli: 5
- Withdrawal to painful stimuli: 4
- Abnormal flexion: 3
- Extends to painful stimuli: 2
- No response: 1

Verbal response
- Oriented: 5
- Confused: 4
- Inappropriate words: 3
- Incomprehensible sounds: 2
- No response: 1

Infection (for source of sepsis)

Site:
- Lungs: (L)
- Soft tissue: (S)
- Abdomen: (A)
- Urinary tract: (U)
- Blood: (B)
- Other: (O)
- Central nervous system: (C)
- Specify: ☐

Organism:
- Gram positive coccus: (C)
- Fungus/yeast: (F)
- Gram positive rod: (R)
- Parasite: (P)
- Gram negative coccus: (K)
- Virus: (V)
- Gram negative rod: (D)
- Other: (O)
- Specify: ☐

Has the antimicrobial(s) changed since ED presentation? Yes (Y) No (N)

If yes

Specify new antimicrobial(s): ☐

Completed by: ☐

Signature: ☐ **Date completed:** D D / M M / 2 0 Y Y

ProMISe

Trial number: | | | | |

Acute hospital – Location/Discharge

Change of location in your hospital

From ED ®

Location*:	**Start date:**	**Start time:** (24-hour clock)
	D D / M M / 2 0 Y Y	H H : M M
	D D / M M / 2 0 Y Y	H H : M M
	D D / M M / 2 0 Y Y	H H : M M
	D D / M M / 2 0 Y Y	H H : M M
	D D / M M / 2 0 Y Y	H H : M M
	D D / M M / 2 0 Y Y	H H : M M

***Location:** *A=Acute Admissions Unit (or equivalent), W=Ward, I=ICU or ICU/HDU, H=HDU, E=Emergency Department, T=Theatre*

Discharge

Acute hospital discharge status (from your hospital): Alive (A) Dead (D)

If alive

Date of discharge: D D / M M / 2 0 Y Y

Discharge location:

- Home: (H)
- Nursing Home: (N)
- Transfer to other hospital: (T)
- Other: (O)
- Specify:

If dead

Date of death: D D / M M / 2 0 Y Y

Time of death: H H : M M

Ultimate discharge from acute hospital:

Status: Alive (A) Dead (D)

Date: D D / M M / 2 0 Y Y

Note: Please obtain Retrospective Consent prior to discharge

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

Acute hospital – Organ support/Co-interventions

ProMISe
Trial number: | | | | |

Organ support in your critical care location

	Total calendar days:		Total calendar days:
Advanced respiratory:		Gastrointestinal:	
Basic respiratory:		Liver:	
Advanced cardiovascular:		Dermatological:	
Basic cardiovascular:		Level 2:	
Renal:		Level 3:	
Neurological:			

Co-interventions (for source of sepsis)

Surgery: Yes (Y) No (N)

If yes Started: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

APC: Yes (Y) No (N)

If yes Started: D D / M M / 2 0 Y Y H H : M M (24-hour clock)
Finished: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

Steroids: Yes (Y) No (N)

If yes Started: D D / M M / 2 0 Y Y H H : M M (24-hour clock)
Finished: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

Comments

Completed by:

Signature: **Date completed:** D D / M M / 2 0 Y Y

PROMISE

Trial number:

Safety monitoring (SOP 016)

(adverse events from randomisation ® 30 days)

Adverse events (specified)

	Severity[1]:	Start date:	Start time: (24-hour clock)	Related[2]:
Pneumothorax:		D D / M M / 2 0 Y Y	H H : M M	
Haemo-pneumothorax:		D D / M M / 2 0 Y Y	H H : M M	
Bleeding:		D D / M M / 2 0 Y Y	H H : M M	
Thrombosis:		D D / M M / 2 0 Y Y	H H : M M	
Pulmonary emboli:		D D / M M / 2 0 Y Y	H H : M M	
Vascular catheter infection:		D D / M M / 2 0 Y Y	H H : M M	
Pulmonary oedema:		D D / M M / 2 0 Y Y	H H : M M	
Blood transfusion reaction:		D D / M M / 2 0 Y Y	H H : M M	
Myocardial ischaemia:		D D / M M / 2 0 Y Y	H H : M M	
Peripheral ischaemia:		D D / M M / 2 0 Y Y	H H : M M	

Adverse events (other)

Adverse event:	Severity[1]:	Start date:	Start time: (24-hour clock)	Related[2]:
		D D / M M / 2 0 Y Y	H H : M M	
		D D / M M / 2 0 Y Y	H H : M M	
		D D / M M / 2 0 Y Y	H H : M M	
		D D / M M / 2 0 Y Y	H H : M M	
		D D / M M / 2 0 Y Y	H H : M M	

[1]*Severity:* *0=None, 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal*

[2]*Related (to trial treatment):* *0=None, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely*

Note: If Severity 3 or more, complete the Serious Adverse Event Reporting Form and fax to ICNARC CTU

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

ProMISe

Trial number: | | | | |

Retrospective consent

Retrospective consent

Regained mental capacity: Yes (Y) No (N)

Retrospective consent:

- Obtained (O)
- Part-obtained (P)
- Refused (R)
- Not sought (N)

Date: D D / M M / 2 0 Y Y

If part-obtained/ not sought

Details:

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

Death notification

PrOMISe

Trial number:

Investigator number:

Death

Date of death: D D / M M / 2 0 Y Y

If completed, return to ICNARC CTU

By fax: [redacted]
By email: [redacted]
By post: [redacted]

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y

Withdrawal of consent/agreement

ProMISe

Trial number: | | | | |

Investigator number: | | |

Withdrawal of consent/agreement

Date of withdrawal: D D / M M / 2 0 Y Y

Reason (if available):

Consent/agreement withdrawn by:

- Patient 1
- Personal Consultee 2
- Professional Consultee 3

If completed, return to ICNARC CTU

By fax: [redacted]
By email: [redacted]
By post: [redacted]

Comments

Completed by:

Signature:

Date completed: D D / M M / 2 0 Y Y