

Inhospital CRF

Emergency department

1) Hospital

- Södersjukhuset KS Solna Medizinische Universität Wien Medizinischen Universität Graz
 Universitätsklinikum Freiburg: Uniklinikum Universitätsmedizin Halle Asklepios Südpfalzlinik
Kandel Hospital Universitario La Paz Hospital Clinico San Carlos Univerzitetni Klinični Ljubljana
 Univerzitetni Klinični Maribor Other

2) Time of hospital arrival

3) ROSC sustained until hospital arrival?
(ROSC sustained until arrival at the hospital and care has been transferred to medical staff at the receiving hospital.)

- Yes No

4) Admitted alive?
(Admitted with ROSC or ROC (return of circulation supported by extracorporeal CPR))

- Yes No

5) Patient declared dead at emergency department

- Yes No

6) ECPR (extracorporeal CPR) performed?

- Yes No

7) Time of ROSC or ROC (return of circulation supported by extracorporeal CPR) if ROSC/ROC after hospital arrival

First registered vital functions upon arrival to hospital (in ER, ICU or other location)

8) Systolic blood pressure (mmHg)

9) Diastolic blood pressure (mmHg)

10) Mean arterial pressure (MAP) (mmHg)

11) Spontaneous breathing

- Yes No
-

12) Glasgow Coma Scale (GCS)

- 3 4 5 6 7 8 9 10 11 12 13 14 15
-

13) Pupillary response

- Present bilaterally
 Absent bilaterally
 Absent unilaterally
 Not assessed
-

14) Tympanic temperature (°C)

15) Time of first registered tympanic temperature

16) Core temperature (°C) (first registered)

17) Time of first registered core temperature

18) Core temperature location

- Rectal
 Bladder
 Esophageal
 Blood
-

19) ECG findings (first ECG post-ROSC)

- STEMI (>1mm ST elevation in ≥ 2 leads)
 New LBBB
 ST-segment depression (>1 mm in ≥ 2 leads)
 None of the above
 Other

First arterial blood gas available after ROSC

20) pH

Conversion of mmHg to kPa
mmHg value * 0.133322

21) pO2 (kPa)

22) pCO2 (kPa)

23) Base excess (mmol/L)

24) Lactate (mg/dl)

25) O2-saturation (%)

26) Hb (g/dl)

27) B-glucose (mmol/L)

SOFA Score

Conversion of mmHg to kPa
mmHg value * 0.133322










Admission Day 1 Day 2 Day 3
PaO2 _____
Fraction Inspired Oxygen (%) _____
Creatinine _____
Glasgow Coma Scale _____
Bilirubin (mg/dL) _____
Platelet count ($\times 10^9/L$) _____
Cardiovascular function (check one) _____

Patients status prior to cardiac arrest (e.g. prior to randomization)

28) Previous (before cardiac arrest) know co-morbidity
(Check all that apply)

- Ischeamic heart disease
- Previous myocardial infarction
- Heart failure
- Atrial fibrillation/flutter
- Hypertension
- Diabetes type 1
- Diabetes type 2
- Chronic kidney disease
- Chronic liver disease
- Cancer
- Stroke/TIA
- Chronic obstructive pulmonary disease
- HIV
- None of the above

Clinical Frailty Scale

| | |
|---|---|
| <p>1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.</p> |  |
| <p>2 Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</p> |  |
| <p>3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.</p> |  |
| <p>4 Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up" and/or being tired during the day.</p> |  |
| <p>5 Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.</p> |  |
| <p>6 Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.</p> |  |
| <p>7 Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).</p> |  |
| <p>8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.</p> |  |
| <p>9 Terminally Ill – Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.</p> |  |

29) Clinical Frailty Scale before OHCA

- 1 Very Fit - People who are robust, active, energetic and motivated
 2 Well - People who have no active disease symptoms but are less fit than category 1
 3 Managing Well - People whose medical problems are well controlled, but are not regularly active beyond routine walking.
 4 Vulnerable - While not dependent on others for daily help, often symptoms limit activities.
 5 Mildly Frail - These people often have more evident slowing, and need help in high order IADLs
 6 Moderately Frail - People need help with all outside activities and with keeping house.
 7 Severely Frail - Completely dependent for personal care, from whatever cause (physical or cognitive)
 8 Very Severely Frail - Completely dependent, approaching the end of life. T
 9 Terminally Ill - Approaching the end of life.

30) Estimated pre-arrest mRS - see Follow-up manuals for more details on mRS princess2.org/manuals

- 0 - No neurological symptoms
 1 - No significant neurological symptoms. Able to carry out usual activities, despite some symptoms
 2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities
 3 - Moderate disability. Requires some help, but able to walk unassisted
 4 - Moderate severe disability. Unable to attend to own bodily needs without assistance or unable to walk unassisted
 5 - Severe disability. Requires constant nursing care and attention, bedridden, incontinent

Core variables for systemic hypothermia in the intervention group

31) Cooling method

- Intravenous system
 Surface system

32) Time of initiation of systemic cooling

33) Was trans-nasal cooling interrupted prior to systemic cooling?

- Yes
 No

34) If trans-nasal cooling was interrupted, please specify reason

35) Time of termination of trans-nasal cooling

Register core temperature and tympanic temperature every 20 minutes from start of systemic cooling until target temperature is reached, if not already at target temperature when systemic cooling is initiated.

Minutes from start of systemic cooling Core temperature

Start _____
 20 _____
 40 _____
 60 _____
 80 (1 h, 20 min) _____
 100 (1 h, 40 min) _____
 120 (2 h) _____
 140 (2 h, 20 min) _____
 160 (2 h, 40 min) _____
 180 (3 h) _____

- 180 (3 h) _____
- 200 (3 h, 20 min) _____
- 220 (3 h, 40 min) _____
- 240 (4 h) _____
- 260 (4 h, 20 min) _____
- 280 (4 h, 40 min) _____

36) Time of core temperature ≤ 34 °C

37) Time of Core temperature ≤ 33 °C

Register core temperature every hour during maintenance phase (start registration 1 hour after target temperature is reached)

Core temperature

- Hour 1 _____
- Hour 2 _____
- Hour 3 _____
- Hour 4 _____
- Hour 5 _____
- Hour 6 _____
- Hour 7 _____
- Hour 8 _____
- Hour 9 _____
- Hour 10 _____
- Hour 11 _____
- Hour 12 _____
- Hour 13 _____
- Hour 14 _____
- Hour 15 _____
- Hour 16 _____
- Hour 17 _____
- Hour 18 _____
- Hour 19 _____
- Hour 20 _____
- Hour 21 _____
- Hour 22 _____
- Hour 23 _____
- Hour 24 _____

38) Time of termination of systemic cooling (start of rewarming)

39) Time of core temperature ≥ 36.5 °C

40) Did the patient have fever >37.7 °C during the first 72 hours (one measurement of core body temperature >37.7 °C)

- Yes No

Echocardiography findings

41) LVEF (%) at 24 hours (+/- 12 hours)

- Normal (> 55%)
- Mildly reduced (45-54%)
- Moderately reduced (30-44%)
- Severely reduced (< 30%)
- Not performed

42) LVEF (%) at 72 hours (+/- 12 hours)

- Normal (> 55%)
- Mildly reduced (45-54%)
- Moderately reduced (30-44%)
- Severely reduced (< 30%)
- Not performed

Serious adverse events within 7 days

43) Moderate bleeding, according to the GUSTO criteria (bleeding requiring transfusion, but not resulting in haemodynamic compromise)

- Yes No

44) Severe bleeding according to Gusto criteria (intracranial hemorrhage or bleeding resulting in haemodynamic compromise necessitating intervention)

- Yes
 No

45) Sepsis and septic shock, according to the 3rd international consensus definitions for sepsis and septic shock?

- Yes No

46) Arrhythmia resulting in hemodynamic compromise?

- No
- Bradycardia with need for pacing
- Ventricular tachycardia
- Ventricular fibrillation

47) Cerebrovascular lesion during ICU stay

- Yes No

48) New cardiac arrest after enrollment (requiring CPR/defibrillation)

- Yes
 No

49) Circulatory complications?

- No
- Cardiogenic shock requiring inotropes
- Cardiogenic shock requiring mechanical support

50) Cooling device related adverse events

- Yes
 No
 Uncertain (needs adjudication)
-

51) If Yes, Specify

52) Did device related or other unexpected serious adverse event occur?

- Yes (fill in safety CRF) No
-

Sedation

53) Was the patient sedated 40 h according to protocol?

- Yes No
-

54) If sedation was terminated (including wake-ups) before 40 h from cardiac arrest, describe why

Lab tests (During ICU stay)

55) NSE at 24 hours (if applicable)

56) NSE at 48 hours (if applicable)

57) NSE at 72 hours (if applicable)

58) Maximum level of Troponin T within 24 hours (if used by center)

59) Maximum level of Troponin I within 24 hours (if used by center)

Angiography/Revascularization

- 60) Angiography performed
- Not performed
 - Acute within 24h after admission
 - During ICU/hospital stay

61) PCI_performed

- Yes No

Delirium

- 62) Symptoms of delirium at the time of ICU discharge?
Identified by: ICD-code for delirium, or positive delirium screening with the delirium assessment instrument used at the site (E.g. the CAM-ICU, the Nu-DESC etc.), or delirium described by text in the medical journals (according to the DSM-5 criteria for delirium).

- Yes
- No
- Missing
- Not applicable

- 63) Symptoms of delirium at seven days or later after OHCA?
Identified by: ICD-code for delirium, or positive delirium screening with the delirium assessment instrument used at the site (E.g. the CAM-ICU, the Nu-DESC etc.), or delirium described by text in the medical journals (according to the DSM-5 criteria).

- Yes
- No
- Missing
- Not applicable

Organ support during ICU stay

- 64) Was the patient supported by an intra-aortic ballon pump (IABP)

- Yes No

- 65) Was the patient supported by ECMO?

- Yes No

- 66) If yes, was the patient put on ECMO during CPR (ECPR)?

- Yes No

- 67) If supported with ECPR, when was ECMO started?
- _____

- 68) Was the patient supported by an Impella?

- Yes No

69) Was the patient treated with continuous renal replacement therapy?

Yes No

70) Deviation from protocol

Yes No

71) If protocol deviation = Yes, describe

**Prognostication at 72 hours - see manual for Neurologic prognostication
princess2.org/manuals**

72) Time for prognostication

73) Does the patient fulfill the study criteria for a likely poor neurological outcome?

Yes
 No

74) What prognostic methods beyond clinical neurological assessment were used for prognostication?
(tick all that apply)

- NSE
 SSEP
 EEG
 MR/CT brain scan

Withdrawal of life sustaining therapies / ICU care discontinued

75) When was intensive care terminated?

76) What prognostic methods beyond clinical neurological assessment were used in the event that intensive care was discontinued?
(tick all that apply)

- NSE
 SSEP
 EEG
 MR/CT brain scan

77) If intensive care was discontinued before 72 hours from randomization, describe why?

Discharge

78) Did patient die during hospital stay?

- Yes (fill in below)
 No
-

79) If yes, where did the patient die

- ICU
 Hospital ward
-

80) Cause of death

- Cerebral
 Cardiac
 Infection
 Multi-organ failure
 Other
-

81) Date and time of discharge

82) mRS at hospital discharge - see follow up manual for more information of mRS princess2.org/manuals

- 0 - No neurological symptoms.
 1 - No significant neurological symptoms.
 2 - Slight disability.
 3 - Moderate disability.
 4 - Moderate severe disability.
 5 - Severe disability.
-

83) Patient discharged to

- Home
 Rehabilitation
 Other