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Description automatically generated

Patient ID -

**SepTiC Eligibility form**

Complete this form as part of the screening process for the SepTiC trial – to be completed by a clinician and filed in the medical records once complete.

|  |  |  |
| --- | --- | --- |
| **Inclusion Criteria** | **Please circle which apply** | |
| Adults (≥16 years of age) admitted to ICU due to suspected sepsis and expected to stay for at least two calendar days (i.e. expected to still to be in ICU the day after tomorrow) | Yes | No |
| Receiving intravenous antibiotics for suspected sepsis | Yes | No |
| According to local clinical judgement, patient has received adequate initial early fluid resuscitation | Yes | No |

|  |  |  |
| --- | --- | --- |
| **Exclusion Criteria** | **Please circle which apply** | |
| More than 24 hours since ICU admission (this does NOT apply for intervention 3, GM-CSF). | Yes | No |
| Previously admitted to ICU due to sepsis on this hospital admission | Yes | No |
| Not expected to survive 90 days, due to pre-existing chronic (end-stage) disease | Yes | No |
| Not expected to survive initial resuscitation (24 hours) | Yes | No |
| Neutropaenia (<0.5 neutrophils x109 /L) due to chemotherapy/malignancy (but not due to sepsis) | Yes | No |
| A source of infection that will require a prolonged course of antibiotics, for greater than 21 days (e.g., infective endocarditis, osteomyelitis, hepatic or cerebral abscess, tuberculosis) | Yes | No |
| Diabetic ketoacidosis (DKA) or hyperglycaemic hyperosmolar state (HHS) | Yes | No |
| Within 21 days of a spontaneous subarachnoid haemorrhage | Yes | No |
| Diabetes Insipidus | Yes | No |
| Weight <40Kg | Yes | No |

**Is the subject eligible to participate in the fluid and diagnostic arms of the study? YES / NO**

I confirm that patient (name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

has been screened for the SepTiC study and is suitable to be enrolled.

Form completed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_/\_\_\_\_/\_\_\_\_ (date)

To complete eligibility for the GM-CSF please complete page 2 of this form.

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Description automatically generated ­­**SepTiC – Additional eligibility for GM-CSF only**

Complete this form as part of the screening process for the GM-CSF trial only (can be done only after initial entry)

|  |  |  |
| --- | --- | --- |
| **Inclusion Criteria** | **Please circle which apply** | |
| Intubated and mechanically ventilated and expected to continue for another 24 hours **or** requiring two organ support (i.e. vasopressors or renal replacement therapy) | Yes | No |
| An absolute lymphocyte count < 1.2 x109/L on two consecutive calendar days at least 12 hours apart, with no values >1.2 x109/L in between. | Yes | No |

|  |  |  |
| --- | --- | --- |
| **Exclusion Criteria** | **Please circle which apply** | |
| More than 120 hours (5 days) since ICU admission | Yes | No |
| Already receiving G-CSF or GM-CSF | Yes | No |
| A total white blood cell count (WBC) >50 x109 /L | Yes | No |
| Allergy, anaphylaxis or previous adverse reaction to GM-CSF or yeast-derived products | Yes | No |
| Known to be pregnant or breastfeeding | Yes | No |
| Known recent (required treatment within the last 5 years) haematological malignancy | Yes | No |
| Solid organ or bone marrow transplantation | Yes | No |
| Patient weight >125kg | Yes | No |

**Is the subject eligible to participate in the GM-CSF arm of the study? YES / NO**

I confirm that patient (name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

has been screened for the SepTiC study and is suitable to be enrolled.

Form completed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_/\_\_\_\_/\_\_\_\_ (date)