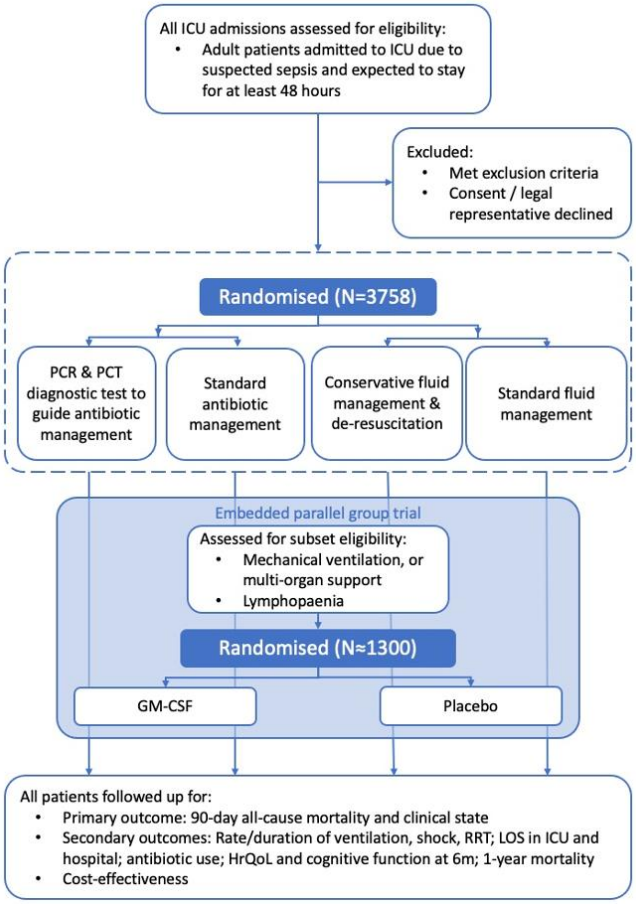
IMP Prescriber Overview

This document should be reviewed by the clinical team who will be prescribing IMP to SepTiC patients. Before the prescription is written please review the following overview for the SepTiC Trial. For any questions please either raise with your local research team or contact the SepTiC Trial team: - septic@imperial.ac.uk

SepTiC is A multi-centre, pragmatic, multi-factorial, open-label randomised controlled trial, with an embedded randomised, double-blind, parallel group trial – see diagram below left.



You are being asked to prescribe the SepTiC IMP for a patient that meets the following criteria:-

This patient **is: -**

- An adult >16yrs admitted to ICU due to suspected sepsis and expected to still be in ICU the day after tomorrow
- Is receiving IV antibiotics for suspected sepsis
- According to local clinical judgement, patient has received adequate initial early fluid resuscitation
- Intubated, mechanically ventilated & expected to continue for another 24 hours **OR**
- Receiving two modes of organ support (Vasopressors, RRT) **AND**
- An absolute lymphocyte count <1.2 x10^9 /L on two consecutive calendar days

This patient is now eligible to receive the IMP. **Please sign the Prescriber Overview training log** to confirm you have read and understood this overview.

Please generate a prescription for this IMP to ensure the bedside nurse can administer. Please note 'SepTiC Trial' on the prescription

This patient **has not/is not /does not**

- Been admitted to ICU more than 120hrs ago
- Been previously admitted to ICU due to sepsis on this hospital admission
- Expected to survive 90 days, due to pre-existing chronic disease
- Expected to survive initial resuscitation (24 hours)
- Neutropaenic due to chemotherapy / malignancy (but not due to sepsis)
- Have a source of infection that will require a prolonged course of antibiotics, for >21 days (e.g. infective endocarditis, osteomyelitis, hepatic or cerebral abscess, tuberculosis)
- Had a DKA / HHS / DI / SAH (in last 21 days)
- Weigh <40Kg or >125kg
- Already receiving G-CSF or GM-CSF
- A total white blood cell count >50 x10^9 /L
- Allergy or previous adverse reaction to GM-CSF
- Known to be pregnant or breastfeeding
- Known recent (required treatment within the last 5 years) haematological malignancy
- Solid organ or bone marrow transplantation
- Known anaphylaxis to GM-CSF or yeast-derived products