Imperial College London

SepTiC

Sepsis Trials in Critical Care

# IMP Administration Training

V1.0 19th March 2024

**This training is for bedside nurses who will be administering the IMP to patients for the SepTiC Study.**

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Chief Investigator: Prof Anthony Gordon
Study Coordination Centre:
Imperial Clinical Trials Unit

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# Coordinating Centre / Trial Management Team

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# Overview of the Study

SepTiC
Sepsis Trials in Critical Care

- The **SepTiC** research study looks to answer three important questions to help treat people with sepsis, the study has three interventions:
- **Intervention 1** : Diagnostic – Using PCR diagnostic test & PCT results to guide antibiotic management vs Standard Care
- **Intervention 2** : Fluid – Conservative fluid management and de-resuscitation vs Standard Care
- **Intervention 3** : GM-CSF - IMP and matching placebo
  - The GM-CSF intervention is aimed at more seriously ill patients with sepsis and low white blood cell count, patients will be randomised to this intervention up to 5 days after ICU admission and when randomised will be given the drug/placebo for 8 days.
  - This intervention is double blinded meaning that there is no distinguishment between the placebo and the IMP

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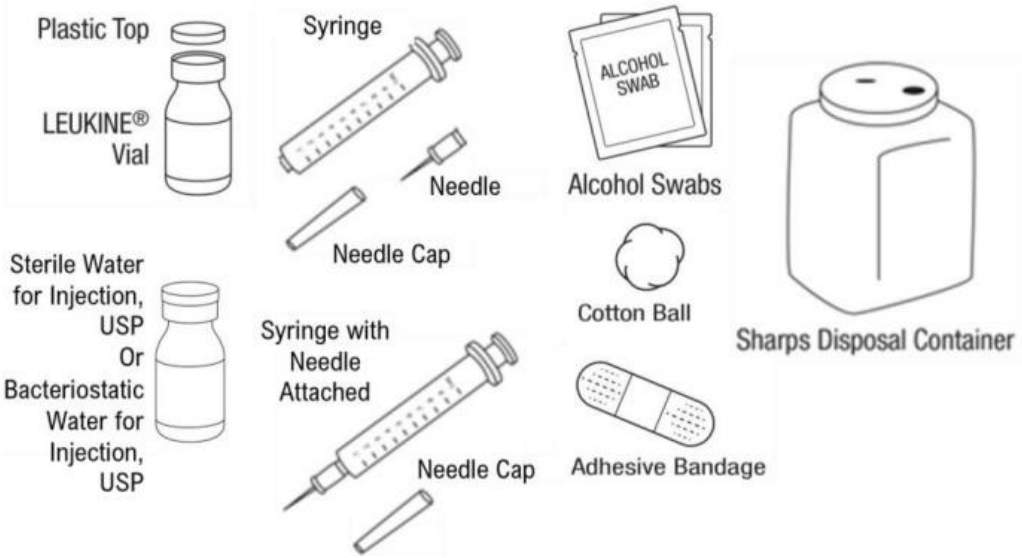
# IMP Randomisation/Allocation

- Randomisation will be performed by site staff on the eCRF, and the patient will be allocated a kit code
- The relevant kit will be taken form the ICU fridge and the patient study ID should be written on each individual vial and outer box and stored by the patient's bedside (un-reconstituted) for the duration of the treatment
- One kit will consist of two boxes cellophaned together with each box containing 8 vials (totalling 16 vials combined from both kits)
- Each vial contains 250µg of lyophilized IMP, the dose of IMP depends on the weight of the patient:
- **50-125 Kg - 500µg (2 vials) subcutaneous injection once a day for 8 days**
- **<50 Kg - 250µg (1 vial) subcutaneous injection once a day for 8 days**

# IMP Preparation: Gather supplies

- Gather supplies needed for your injection:

- IMP vial (2 Vials if patient is  50-125kg)
- Vial of liquid to add to the powdered IMP vial (Sterile Water for Injection or Bacteriostatic Water for Injection – 1ml fluid per vial of IMP)
- Syringe and needle (leave cap on) to add the liquid to the IMP vial
- Syringe and needle (leave cap on) to inject the IMP dose
- Alcohol swabs
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



# IMP Preparation– Reconstitution

1. The IMP vial/s should be taken out of the fridge before use and allowed to reach room temperature before preparing an injection. If the kit is at the bed side, this will be at room temperature already
2. The vial should be reconstituted with Sterile Water for Injection or Bacteriostatic Water for Injection
3. 1ml of liquid (without air) is used to reconstitute 1 vial of the IMP. The IMP should be reconstituted using aseptic non touch technique.
4. Gently roll the vial between your palms until the until the powder is completely dissolved and the solution is clear and colourless. Do not shake the vial.
5. Use the vial immediately and only one time. Do not save partially used IMP vials for later use.

*** For more information on the reconstitution process please see the IMP Handling Manual**

# Prepare the dose

1. Locate the needle, syringe and vial of liquid IMP to inject
2. Push the syringe plunger down and inject all the air from the syringe into the vial. Keep your finger on the plunger so air does not come back into the syringe
3. Keep the needle in the vial and turn the vial upside down. Make sure the liquid is covering the needle tip.
4. Keep the vial upside down and slowly pull back on the syringe plunger to fill the syringe barrel with the IMP. Keep the tip of the needle in the liquid (ensure there are no bubbles in the syringe).
5. Keep the needle tip in the liquid and again pull the plunger back to the number on the syringe barrel that matches your dose (mL). Repeat these steps as needed if there are still air bubbles in the syringe.
6. **DO NOT** remove the needle from the vial yet.
7. Lie the vial down on its side with the needle still in the vial
8. First select and prepare the injection site…….

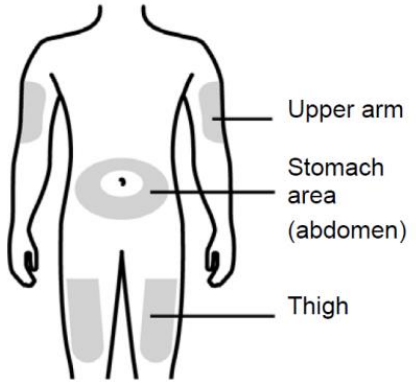
# IMP Administration – Injection

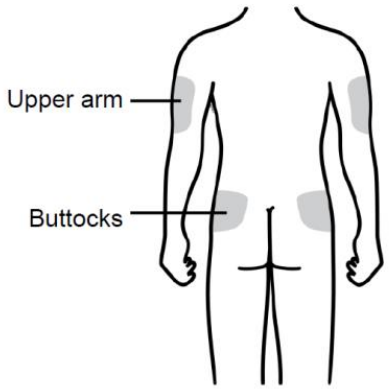
The injection is subcutaneous and can be administered in the following areas:

- Thigh
- Stomach area (abdomen), except for a 2-inch area

right around your navel (bellybutton)

- Upper outer area of the buttocks
- Outer area of upper arm




- **Use the vial immediately and only one time. Do not save partially used IMP vials for later use.**
- The IMP should be given once a day, this doesn't have to be at the same time every day however the suggestion would be to administer the IMP at roughly the same time every day. Ensure 12 hours minimum between doses.
- For patients over 50kg, two vials are used per injection - It is up to the site to decide whether they would like to administer the IMP as one injection per vial (reconstitute each vial separately) or administer one injection (reconstitute two vials in one syringe)

# IMP – Disposal of Vials + Accountability

- Used vials can be disposed of by the site team, there is no need to complete a returns form nor a destruction log.
- Once the patient has finished their 8-day course, complete the Accountability Log with the total number of vials used.
- If the patient is discharged from ICU within the 8 days site staff are encouraged to continue the treatment on the ward up until day 8 – movement of IMP from ICU to the ward will be facilitated by research nurses.

- For all FAQs regarding GM-CSF please see our study page: FAQ's (septictrial.co.uk)