

Category: Handling and Maintenance of equipment of Phase I unit

Title: Procedure to use Infusion pump

SOP No.: DCP/Ph1/003

Date first effective: 01 Jan 2024

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Title: Procedure to use and Maintain Infusion pump

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1. Purpose

The purpose of this SOP is to describe the procedure for handling and maintaining the infusion pump in Phase 1 unit of Department of Clinical Pharmacology,

2. Scope

This SOP applies to handling and maintaining of infusion pump in Phase 1 unit.

3. Responsibilities

Principal investigator [PI], Co-Investigator(s), study coordinator or any other medically qualified member as delegated by PI will be responsible to follow the procedures to determine the vital parameters of the participants admitted in phase 1 unit. It is also need to be ensured that the equipment is appropriately cleaned, maintained in good working order, and available for research personnel as requested.

4. Detailed Instructions

4.1 Approach to participant

- The investigator or the delegated person will refer to the protocol to ensure specific requirements of vital parameters in the participant.
- The investigator or the delegated person will explain the procedure to the participant.
- The investigator or the delegated person must ensure participant comfort and the participant is warm enough
- The investigator or the delegated person should wash their hands according to Hand Hygiene Policy.

4.2 Handling of Infusion Pump

- Prior assessment of the participant should be done including his/her vital signs and note the same in the Participant in-patient sheet/medical records.
- Investigator/Designee should assess the participant to ensure that he/she meets the eligibility criteria, if the infusion pump has to be used for any study related procedure
- Physician's written and signed order for the infusion should be confirmed a priori in case of treatment of any medical emergency

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- Prior to infusion, the medical officer should ensure that the infusion pump is functioning properly
- The electrical cords should be connected and the infusion pump is placed in the infusion pump holder at the appropriate heights.
- The medication to be used in continuous infusion pump is to be used in 50 cc syringe. And the syringe should be labelled with the name of the drug, its concentration and the rate it is to be given.
- The mentioned concentration of the drug should be made using 0.9 % Normal Saline or Ringer Lactate or as mentioned by the manufacturer and should be filled in the 50 cc syringe.
- The concentration should be made using all aseptic precautions.
- Settings (name of drug, rate & volume of infusion, whether infusion/bolus, type of syringe) must be done in the infusion pump before starting the infusion
- Pump screen should be checked to ensure that the programmed rates and dose matches with the medicine label.
- Medical officer should make sure that the infusion set is properly connected to a three-way stop clock on the patient's intravenous line
- Note the start time and end time of infusion in the participant sheet
- If an alarm is heard during infusion/bolus, the medical officer should attempt to correct the problem.
- If there is block then the IV canula should be flushed with 5 ml 0.9% NS and again the infusion should be started.
- If the IV canula is blocked or came out of the vein then a new IV canulation to be done before re-starting the infusion.
- If the problem cannot be remedied, the medical officer/nurse should press the start / stop button to turn off the infusion. Call the physician/ duty doctor on call for any help

4.3 Maintenance of Infusion pump

- The infusion pump should always be placed on a clean surface.
- Food and beverages should be kept away from the area around the pump.
- Hands should be washed thoroughly for 15 seconds before touching the pump
- If requires, the tube should be changed according to pump's Instruction manual for use.

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- In case of over- or under-infusion, tube should be checked for any leakage, links twists and disconnects
- Clamps should be checked once a week to detect any occlusion
- The pump should be decontaminated with a mild disinfectant solution
- Care must be taken not to wipe the display screen with any harsh chemicals as it may permanently damage the screen
- In case of any other issue the infusion pump should be checked by their respective company personnel for faults and it should be repaired at the earliest with dates of the repair to be mentioned.

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