Standard Operating Procedure (SOP)
Management of Control Group Patients
SOP 002

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Scope

- To provide guidance on management of patients who have been allocated to the control group in the OPTIMISE II Trial.

Procedure

- Following induction of anaesthesia, patients allocated to the control group will be managed by the clinical staff according to usual practice at their sites.

Monitoring

- Patients should not be randomised if the clinician intends to use cardiac output monitoring regardless of study group allocation; this is considered 'clinician refusal' and is a specific exclusion criteria. However, clinical staff are able to request cardiac output monitoring if this is required to inform the treatment of a patient who becomes critically ill (e.g. because of severe haemorrhage); in this situation a protocol deviation form will be completed.
- If a specific haemodynamic end-point for fluid challenges is to be used, the most appropriate would usually be a sustained rise in central venous pressure of at least 2 mmHg for 20 minutes or more.

General haemodynamic measures

Care for all patients has been loosely defined to avoid extremes of clinical practice but also practice misalignment, as follows:

- Patients will receive 5% glucose at 1 ml/kg/hr as maintenance fluid.

- Additional fluid will be administered at the discretion of the clinician, guided by the pulse rate, arterial pressure, urine output, core-peripheral temperature gradient, serum lactate and base deficit/excess.
- For fluid challenges, 250ml of one of the following solutions should be used:
    - "Balanced" crystalloid: Hartmann's solution (compound sodium lactate, Ringer's lactate), Plasmalyte 147.
    - 0.9% sodium chloride
    - Gelatin-based colloid
    - Starch-based colloid
    - Albumin

- Blood will be transfused to maintain haemoglobin at greater than 8 g/dl.
- Oxygenation will be maintained at $Sp0_2$ 94% or greater.
- Heart rate will be maintained at less than 100 beats per minute.
- Core temperature will be maintained at 37°C.
- Mean arterial pressure will be maintained between 60 and 100 mmHg using an alpha adrenoceptor agonist or vasodilator as required, although other measures such as adjustments to anaesthesia and analgesia should be considered first.

Post-operative analgesia and sedation

- Post-operative analgesia will be provided at the discretion of the clinician in accordance with local protocols. This may include epidural infusion (bupivicaine and fentanyl), intrathecal opioids (fentanyl, morphine, diamorphine), wound catheter infusion (bupivacaine), opioid-based patient-controlled analgesia system, oral analgesics (including opioids) or intra-venous infusion (opioids or lidocaine).
- If required, post-operative sedation will be provided with propofol or midazolam.

Plasma potassium and glucose monitoring

- Monitoring of plasma potassium and glucose levels is recommended.