Standard Operating Procedure (SOP)

Patient infection follow-up

SOP 005

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Scope

- To describe the process for collection of infection outcome data for trial participants in an objective and blinded manner. To be read in conjunction with the SOP for serious adverse event reporting.

Background

- The primary outcome measure for the OPTIMISE II trial is the number of patients who develop infections within 30 days of randomisation. Objective and blinded assessment of this outcome is an important aspect of the methodology of the trial.
- A list of detailed definitions of complications is presented in the protocol, appendix 1. It is expected that these definitions will cover more than 90% of the complications detected during the conduct of the trial.

Appropriate documentation to maintain blinding

- A patient's participation in the OPTIMISE II trial will be documented in the notes without revealing study group allocation. A patient's participation in the OPTIMISE II trial will be documented on the anaesthetic chart with the words 'Participant in the OPTIMISE II Trial: see notes'.
- The only clinical document which will reveal a participating patient's study group allocation will be the drug chart. This will include an adhesive label providing the necessary information regarding the prescription and administration of dopexamine or dobutamine. A label will only be placed in the drug chart for intervention group patients and the drug chart will therefore identify the study group allocation of the patient.

- The use or omission of cardiac output monitoring or the administration of dopexamine or dobutamine will not be recorded on the anaesthetic chart in order not to identify the study group allocation of the patient.
- The use or omission of cardiac output monitoring or the administration of dopexamine or dobutamine will be recorded by local investigators in the patient's case report form.
- Information regarding the administration of dopexamine or dobutamine is therefore freely available to clinical staff should they require it.
- Volumes and types of intra-venous fluid administered to patients will be recorded on clinical documents according to local policies. Previous experience confirms that this information does not allow identification of study group allocation.

Blinded assessment of infection

- The local investigator(s) responsible for assessment of clinical outcomes must be unaware of the study group allocation of any given participant. Hence the local investigator(s) responsible for randomising and overseeing the delivery of the trial intervention cannot also assess complications but can assist in providing blinded clinical data for others to do so.
- Wherever possible, knowledge of study group allocation should be confined to those local investigators who are undertaking randomisation, delivery or oversight of the intervention. This information should not be revealed to others, for example curious clinical staff.
- The local investigator(s) responsible for assessment of clinical outcomes will be unaware of study group allocation provided they do not inspect the drug chart and are not informed of this information by other local investigators. As information regarding drug treatment is required in some cases to assess the outcome of complications, another local investigator (or a member of clinical staff) must therefore inspect the drug chart and provide any relevant information (most commonly the prescription of antibiotics) to the local investigator assessing complications without revealing the study group allocation.
- The local investigator assessing the clinical outcomes will record any relevant information required to confirm a given complication has occurred. Experience suggests that brief but regular visits to the ward every few days are the most effective approach.

Follow-up of infection outcome

- Outcome data will be collected at three stages during the trial:
    - 24 hours: through patient's medical notes
    - 30 days: through patient's medical notes, collected through conversation with patients following discharge and contact with patient's primary care physicians, the surgical team or other medical professionals involved in care
    - 180 days: through patient's medical notes and collected through conversation with patients following discharge

  Please refer to the protocol for a detailed list of the outcome data point and the corresponding definitions (appendix 1).
- Outcome data will be collected through conversation with patients following discharge and contact with patient's primary care physicians, the surgical team or other medical professionals involved in care.
- Missing data may arise if:
    - contact cannot be made with the patient or the patient is unable to confirm whether they have had an infection

      AND
    - neither the primary care physician or surgical team (or other medical teams involved in care) can confirm whether the patient has had an infection or not up to day 30. This could occur if contact cannot be made or if contact can be made but the people contacted do not have/will not give sufficient information on the patient following discharge from hospital.

Verification of infection outcome

- Once the complications outcome has been assessed this must be verified by the principal investigator at each site according to the detailed definitions of complications. The PI verification process should takes only a couple of minutes for each patient provided the relevant clinical data are available.
- Where evidence of complications is incomplete the principal investigator will request the further information before the clinical outcomes for any given patient are verified and then entered onto the database.

- Where the principal investigator has assessed the infection outcome, another local investigator who is a senior clinician should be nominated to verify complications for the patient concerned.
- Where the principal investigator is aware of study group allocation because of involvement in randomisation or delivery / oversight of the trial intervention, another local investigator who is a senior clinician should be nominated to verify complications for the patient concerned.

Grading infections

- All postoperative infections will need to be reported.
- The primary outcome is defined as postoperative infections of Clavien-Dindo grade II or higher.

Clavien-Dindo scale grading:

I. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diruetics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course.

II. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I.

III. Requires surgical, endoscopic or radiological intervention.

IV. Life-threatening complication requiring critical care admission

V. Death

Other

- For each patient, local investigators will confirm whether the guidance in this SOP has been adhered to at the point of data entry onto the case record.