Standard Operating Procedure (SOP)

Safety Reporting

SOP 006

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Scope

- To identify and standardise the process for reporting Serious Adverse Events (SAEs) related to OPTIMISE II trial procedures.
- Previous research on cardiac out monitors suggests that the treatment we are investigating is very safe and is routinely used in clinical practice. However, in order to robustly ensure the safety of trial participants, the trial includes procedures for reporting SAEs to the trial management group.

Serious Adverse Events

- Prompt reporting of SAEs is required to ensure any factors which affect the safety of the trial participants can be identified and acted upon. In the OPTIMISE II trial, an SAE must be assessed by the Principal Investigator (or suitably qualified nominee) as probably or definitely related to the trial procedures and meet at least one of the following criteria:
    a) Results in death
    b) Is life threatening
    c) Clearly prolongs hospital stay
    d) Causes significant disability or incapacity
- Potential SAEs should be reported to the OPTIMISE II trial co-ordinating centre by email (**admin@optimiseii.org**) or online (**https://trials3.pctu.qmul.ac.uk**) within 24 hours. The Chief Investigator will then determine whether an adverse event meets the criteria for an SAE, and consider what further action should be taken if any, to protect current and future trial participants. This may involve discussion with the Principal Investigator concerned, and if necessary, the independent chairs of the Steering and Data Monitoring and Ethics Committee.
- Confirmed SAEs will be reported by the trial management group to the sponsor and/or ethics committee as required by national research regulations for the country in question.

- Individual sites will record SAEs by completing the case report form supplementary document ‘serious adverse event’. This information should be submitted through the online database and paper copies should be kept locally.
- Potential SAEs should be reported within 24 hours. Details of the SAE should be entered into the supplementary form ‘serious adverse event’ section of both the paper and online OPTIMISE II CRF. In addition, an email should be sent to **admin@optimiseii.org** to notify the OPTIMISE II trial co-ordinating centre that a potential SAE has occurred. Please include the participant’s trial number as identification. However, please do not send by email any patient identifiable data (name, date of birth, address etc).
- Additional information may be requested by the OPTIMISE II trial co-ordinating centre, which should be provided within a timely manner.