



**Optimisation of Perioperative Cardiovascular Management to Improve Surgical Outcome II (OPTIMISE II) Trial**

**Study Reference Number: IRAS ID** 209688

**Chief Investigator: Professor Rupert Pearse**

**Principal Investigator: xxxx**

**CASE REPORT FORM**

**Version: 6.0**

**Date: 30/11/2020**

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| **ENROLMENT DATES** | | | |
| Consent date | |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_|  **(DD/MMM/YYYY)** | Date of surgery | |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_|  **(DD/MMM/YYYY)** |

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| **ELIGIBILITY** | **YES** | **NO** |
| **Inclusion criteria** |  |  |
| Age ≥ 65 years | □ | □ |
| Major elective surgery involving the gastrointestinal tract expected to last ≥ 90 minutes | □ | □ |
| **Exclusion criteria** |  |  |
| Inability or refusal to provide informed consent | □ | □ |
| Clinician refusal (including intention to monitor cardiac output regardless of study group) | □ | □ |
| American Society of Anesthesiologists (ASA) physical status score of I | □ | □ |
| Patient expected to die within 30 days | □ | □ |
| Acute myocardial ischaemia within last 30 days | □ | □ |
| Acute pulmonary oedema within last 30 days | □ | □ |
| Contra-indication to low-dose inotropic medication | □ | □ |
| Pregnancy at time of enrolment | □ | □ |
| Previous enrolment in the OPTIMISE II trial | □ | □ |
| Current participation in another clinical trial of a treatment with a similar biological mechanism or primary outcome measure | □ | □ |

**IF ALL ANSWERS ARE ‘YES’ TO THE INCLUSION CRITERIA AND ‘NO’ TO THE EXCLUSION CRITERIA THE PATIENT IS ELIGIBLE. PLEASE SEE PROTOCOL FOR MORE INFORMATION ON INCLUSION CRITERIA.**

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| **Randomisation should only be performed on the day of surgery** |

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| **ASA Physical Status Score** | | |
| Class II □ | Class III □ | Class IV □ |

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| **PLANNED SURGICAL PROCEDURE (single most appropriate)** | **Tick one** |
| Resection of colon, rectum or small bowel | □ |
| Resection of pancreas and bowel | □ |
| Resection of stomach (non-obesity surgery) | □ |
| Resection of oesophagus (non-obesity surgery) | □ |
| Obesity surgery | □ |
| Other major surgery involving gut resection (please specify): | □ |

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| **Planned level of care on the first night after surgery** | **Tick one** |
| Critical care level 3 | □ |
| Critical care level 2 | □ |
| Post-anaesthesia care unit | □ |
| Surgical ward | □ |

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| **LABORATORY TESTS** | **(most recent within 4 weeks before surgery)** |
| Haemoglobin measurement | |\_\_|\_\_|\_\_| g/L |
| Creatinine measurement | |\_\_|\_\_|\_\_|\_\_| μmol/L |
| Ethnicity (for eGFR) | Black or Afro-Caribbean □ Other □ |

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| **Definitions:**  **The level of care should be defined according to the care the patient receives rather than the location:**   * Critical care level 3: care includes advanced organ support e.g. invasive ventilation, renal replacement therapy. * Critical care level 2: care may include advanced cardiorespiratory monitoring (e.g. invasive arterial / central venous monitoring) and basic organ support (e.g. non-invasive ventilation, inotropic/vasoactive drugs). * Post-anaesthetic care unit: designated area for patient care immediately after anaesthesia. * Surgical ward (level 0/1): normal ward care without capability for level 2 or 3 interventions or monitoring. |

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| **CO-MORBID DISEASE** | | **YES** | **NO** |
| 1. | Chronic respiratory disease | | |
|  | Chronic obstructive pulmonary disease (COPD) | □ | □ |
|  | Asthma | □ | □ |
|  | Interstitial lung disease or pulmonary fibrosis | □ | □ |
| 2. | Ischaemic heart disease | □ | □ |
| 3. | Diabetes mellitus | □ | □ |
| 4. | Heart failure | □ | □ |
| 5. | Liver cirrhosis | □ | □ |
| 6. | Active cancer | □ | □ |
|  | If yes – is cancer the indication for surgery? | □ | □ |
| 7. | Previous stroke or transient ischaemic attack | □ | □ |
| 8. | Current smoker (within the last 14 days) | □ | □ |
| 9. | Preoperative immunosuppressant therapy within 30 days before surgery (please tick):  None □ Steroids □ Chemotherapy □ Other immunosuppressant □ | | |

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| **SARS-CoV-2 Test before surgery** | **Tick one** |
| Negative | □ |
| Positive | □ |
| Not Known | □ |
| Date of Test | |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_|  **(DD/MMM/YYYY)** |

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| **PATIENT DEMOGRAPHICS** | | |
| Age | |\_\_|\_\_|\_\_| years | |
|  | | |
| Gender/Sex | Female □ | Male □ |

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| **PHYSICAL MEASUREMENTS** | | | |
| Height (cm): | |\_\_|\_\_|\_\_| | Weight (kg): | |\_\_|\_\_|\_\_| |

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| **STUDY INTERVENTION TIMINGS** | |
| Start of general anaesthesia | DATE: |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_| TIME: |\_\_|\_\_| **:** |\_\_|\_\_|  **(DD/MMM/YYYY) (HR : MINS)** |
| End of surgery | DATE: |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_| TIME: |\_\_|\_\_| **:** |\_\_|\_\_|  **(DD/MMM/YYYY) (HR : MINS)** |
| End of four hour postoperative intervention period | DATE: |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_| TIME: |\_\_|\_\_| **:** |\_\_|\_\_|  **(DD/MMM/YYYY) (HR : MINS)** |

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| **CARDIAC OUTPUT MONITORING** | | | **YES** | | **NO** |
| Did the patient receive cardiac output monitoring during the trial intervention period? | | | □ | | □ |
| If YES, please answer the following questions. If NO, please skip to next section “FLUIDS”. | | | | | |
| Cardiac output monitor used during surgery | EV1000 with FloTrac □ | EV1000 with Clearsight □ | | Other □ (specify): | |
| Cardiac output monitor used after surgery | EV1000 with FloTrac □ | EV1000 with Clearsight □ | | Other □ (specify): | |

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| **FLUIDS** |  |
| **During surgery** |  |
| Primary fluid used for volume replacement **during** surgery |  |
| Primary fluid used for maintenance **during** surgery |  |
| Total volume of intravenous crystalloid **during** surgery: | |\_\_|\_\_|\_\_|\_\_|\_\_| ml |
| Total volume of intravenous colloid **during** surgery: | |\_\_|\_\_|\_\_|\_\_|\_\_| ml |
| Total volume of red cell and other blood products **during** surgery: | |\_\_|\_\_|\_\_|\_\_|\_\_| ml |
|  |  |
| **During four hours after surgery** |  |
| Primary fluid used for volume replacement **after** surgery |  |
| Primary fluid used for maintenance **after** surgery |  |
| Total volume of intravenous crystalloid **after** surgery: | |\_\_|\_\_|\_\_|\_\_|\_\_| ml |
| Total volume of intravenous colloid **after** surgery: | |\_\_|\_\_|\_\_|\_\_|\_\_| ml |
| Total volume of red cells and blood products **after** surgery: | |\_\_|\_\_|\_\_|\_\_|\_\_| ml |

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| **DRUGS** | | | | | | | | | |
| Inotrope infusion used (tick one): | | | | Dobutamine □ | | Dopexamine □ | | | Neither □ |
| If ‘Dobutamine’ or ‘Dopexamine’ please answer the following questions. If ‘Neither’ please skip to next section ‘OTHER INTERVENTIONS’ | | | | | | | | | |
| Infusion start time | DATE: |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_| TIME: |\_\_|\_\_| **:** |\_\_|\_\_|  **(DD/MMM/YYYY) (HR : MINS)** | | | | | | | | |
| Infusion end time | DATE: |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_| TIME: |\_\_|\_\_| **:** |\_\_|\_\_|  **(DD/MMM/YYYY) (HR : MINS)** | | | | | | | | |
| Lowest rate administered | | |\_\_|\_\_| . |\_\_|\_\_| µg.kg-1.min-1 | | | | | | | |
| Highest rate administered | | |\_\_|\_\_| . |\_\_|\_\_| µg.kg-1.min-1 | | | | | | | |
| Infusion rate reduced due to tachycardia? | | | | No □ | Yes (during surgery) □ | | | Yes (after surgery) □ | |
| Infusion site: | | | Central vein □ | | | | Peripheral vein □ | | |

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| **OTHER VASOACTIVE DRUGS** | **YES** | **NO** |
| Did the patient receive any other inotropes or vasopressors by bolus or infusion during the trial intervention period? | □ | □ |
| If YES, please answer the following questions. If NO, please skip to next section ‘RESEARCH STAFF’ | | |
| **Which other drugs were used (tick all that apply)** | **BOLUS** | **INFUSION** |
| Epinephrine (adrenaline) | □ | □ |
| Ephedrine | □ | □ |
| Metaraminol | □ | □ |
| Phenylephrine | □ | □ |
| Norepinephrine (noradrenaline) | □ | □ |
| Dobutamine | □ | □ |
| Dopexamine | □ | □ |
| Dopamine | □ | □ |
| Other | □ | □ |
| If other (please specify): |  | |

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| **SURGICAL PROCEDURE *PERFORMED* (single most appropriate)** | **Tick one** | |
| Resection of colon, rectum or small bowel | □ | |
| Resection of pancreas and bowel | □ | |
| Resection of stomach (non-obesity surgery) | □ | |
| Resection of oesophagus (non-obesity) | □ | |
| Obesity surgery | □ | |
| Other surgery involving gut resection (please specify): | □ | |
| **SURGICAL TECHNIQUE (single most appropriate)** | **Tick one** | |
| Open surgical technique | □ | |
| Laparoscopic or laparoscopic assisted technique | □ | |
| Laparoscopic converted to open | □ | |
| **ANAESTHETIC TECHNIQUE** | **YES** | **NO** |
| General anaesthesia | □ | □ |
| Spinal / epidural | □ | □ |
| Tracheal tube removed at end of surgery? | □ | □ |
| Time spent in post-anaesthesia care unit at end of surgery: | |\_\_|\_\_|**:**|\_\_|\_\_|  **(HR:MINS)** | |
| **LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY** | **Tick one** | |
| Critical care level 3 | □ | |
| Critical care level 2 | □ | |
| Post-anaesthesia care unit | □ | |
| Surgical ward | □ | |

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| **RESEARCH STAFF** | **YES** | **NO** |
| Were additional research staff present to help deliver cardiac output-guided haemodynamic therapy **during surgery**? | □ | □ |
| Were additional research staff present to help deliver cardiac output-guided haemodynamic therapy in the four hours **after surgery**? | □ | □ |

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| **Acute cardiac events** | **I** | **II** | **III** | **IV** | **V** | **NONE** |
| Arrhythmia | □ | □ | □ | □ | □ | □ |
| Myocardial infarction | □ | □ | □ | □ | □ | □ |
| Myocardial injury after non-cardiac surgery | □ | □ | □ | □ | □ | □ |
| Cardiac arrest with successful resuscitation |  |  |  | □ | □ | □ |
| Cardiogenic pulmonary oedema | □ | □ | □ | □ | □ | □ |

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| **Date of follow-up** | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** |

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| **Definitions:**  Please refer to appendix 1 of the protocol appendix for specific definitions of complications. Please grade complications using the Clavien-Dindo scale as follows:   1. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diuretics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course. 2. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I. 3. Requires surgical, endoscopic or radiological intervention. 4. Life-threatening complication (including CNS complication, but excluding transient ischaemic attack) requiring critical care admission   V. Death |

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| **Date of follow-up** | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** |

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| **All of the outcomes in section 6 refer to the 30 day period after randomisation** | |
| **Patient status on date of follow-up** | □ Alive □ Dead Date of death: |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** |

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| **Primary outcome: infection** | **I** | **II** | **III** | **IV** | **V** | **NONE** |
| Surgical site infection (superficial) | □ | □ | □ | □ | □ | □ |
| Surgical site infection (deep) | □ | □ | □ | □ | □ | □ |
| Surgical site infection (organ space) | □ | □ | □ | □ | □ | □ |
| Pneumonia | □ | □ | □ | □ | □ | □ |
| Urinary tract infection | □ | □ | □ | □ | □ | □ |
| Infection, source uncertain | □ | □ | □ | □ | □ | □ |
| Laboratory confirmed blood stream infection | □ | □ | □ | □ | □ | □ |
| **Date of diagnosis of the first postoperative infection (date antibiotic therapy commenced)** | | | | | | |
| |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** | | | | | | |

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| **The PI (or a designee) must verify the primary outcome**  **See ‘Assessment of primary and secondary outcomes’ in the protocol for more information** | | | |
| Name: |  | Signature: |  |

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| **Acute cardiac events** | **I** | **II** | **III** | **IV** | **V** | **NONE** |
| Arrhythmia | □ | □ | □ | □ | □ | □ |
| Myocardial infarction | □ | □ | □ | □ | □ | □ |
| Myocardial injury after non-cardiac surgery | □ | □ | □ | □ | □ | □ |
| Cardiac arrest with successful resuscitation |  |  |  | □ | □ | □ |
| Cardiogenic pulmonary oedema | □ | □ | □ | □ | □ | □ |

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| Please refer to the protocol appendix for specific definitions of complications. Please grade complications using the Clavien-Dindo scale as follows:   1. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diuretics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course. 2. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I. 3. Requires surgical, endoscopic or radiological intervention. 4. Life-threatening complication (including CNS complication, but excluding transient ischaemic attack) requiring critical care admission   V. Death |

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| **Other complications** | **I** | **II** | **III** | **IV** | **V** | **NONE** |
| Acute kidney injury | □ | □ | □ | □ | □ | □ |
| Acute psychosis or delirium | □ | □ | □ | □ | □ | □ |
| Acute Respiratory Distress Syndrome |  |  |  | □ | □ | □ |
| Anaphylaxis | □ | □ | □ | □ | □ | □ |
| Anastomotic breakdown | □ | □ | □ | □ | □ | □ |
| Bowel infarction | □ | □ | □ | □ | □ | □ |
| Gastro-intestinal bleed | □ | □ | □ | □ | □ | □ |
| Multi-organ dysfunction syndrome |  |  |  | □ | □ | □ |
| Paralytic ileus | □ | □ | □ | □ | □ | □ |
| Perforated viscus (e.g. bowel, gall bladder etc) | □ | □ | □ | □ | □ | □ |
| Other postoperative haemorrhage (not GI bleed) | □ | □ | □ | □ | □ | □ |
| Pulmonary embolism | □ | □ | □ | □ | □ | □ |
| Stroke | □ | □ | □ | □ | □ | □ |
| Any other complication, *please give details here:* | □ | □ | □ | □ | □ | □ |

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| **Additional treatments** | **YES** | **NO** |
| Red blood cell transfusion | □ | □ |
| Parenteral (intra-venous) nutrition | □ | □ |
| Endoscopic or radiological intervention | □ | □ |
| Repeat surgery | □ | □ |
| If YES, please indicate the reason for repeat surgery | | |
| Infection | □ | □ |
| Bleeding | □ | □ |
| Anastomotic leak | □ | □ |
| Other | □ | □ |
| Unplanned critical care admission to treat a complication | □ | □ |
| Planned critical care admission prolonged to treat a complication | □ | □ |
| Invasive mechanical ventilation after leaving the operating room | □ | □ |
| If YES, what was the total duration of invasive mechanical ventilation? | |\_\_|\_\_|\_\_| hours | |

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| **Patients admitted to a critical care unit** |  | |
| What was the total duration of the level 2 critical care stay within 30 days of randomisation? | |\_\_|\_\_| days | |
| What was the total duration of the level 3 critical care stay within 30 days of randomisation? | |\_\_|\_\_| days | |
| **Details of the hospital stay** |  | |
| Did the patient survive to discharge of primary hospital admission? | Yes □ | No □ |
| Duration of primary hospital admission (from randomisation) | |\_\_|\_\_| days | |
| Re-admission to hospital within 30 days of randomisation | Yes □ | No □ |

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| **Post-operative SARS-CoV-2** | **YES** | **NO** | **Not Known** |
| Respiratory failure was associated with a positive SARS-CoV-2 test result? | □ | □ | □ |
| Any other complication was associated with a positive SARS-CoV-2 test result? | □ | □ | □ |

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| **Self-assessment of blinding by investigator that collectedfollow up data** | |
| I was suitably blinded | □ |
| I may have known the study group allocation | □ |
| I definitely knew the study group allocation | □ |

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| If primary hospital admission is longer than 30-days, please enter the total duration.  The self-assessment of blinding only applies to data collection at this time point. This self-assessment should be completed by the investigator *collecting* the 30-day outcome data, not the person entering them online (if different).  **The level of care should be defined according to the care the patient received rather than the location:**   * Critical care level 3: care includes advanced organ support e.g. invasive ventilation, renal replacement therapy. * Critical care level 2: care may include advanced cardiorespiratory monitoring (e.g. invasive arterial / central venous monitoring) and basic organ support (e.g. non-invasive ventilation, inotropic/vasoactive drugs). * Post-anaesthetic care unit: designated area for patient care immediately after anaesthesia. * Surgical ward (level 0/1): normal ward care without capability for level 2 or 3 interventions or monitoring. |

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| **Date of follow-up** | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** |
| **Patient status at follow-up** | □ Alive □ Dead: date of death: |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** |

**ONLY COMPLETE THIS FORM IF THERE IS A PROTOCOL DEVIATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant in the intervention group did NOT receive cardiac output monitoring** | **State when this occurred:** | | |
| Please indicate the reason (tick one) | During surgery | After surgery | During AND after surgery |
| Clinician decision | □ | □ | □ |
| Equipment related | □ | □ | □ |
| Communication error | □ | □ | □ |
| Other (please specify): | □ | □ | □ |

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| **Participant in the intervention group did NOT receive inotrope infusion, or received incorrect dose** | **State when this occurred:** | | |
| Please indicate the reason (tick one) | During surgery | After surgery | During AND after surgery |
| Clinician decision | □ | □ | □ |
| Equipment related | □ | □ | □ |
| Communication error | □ | □ | □ |
| Other (please specify): | □ | □ | □ |

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| **Participant in the control group DID receive cardiac output monitoring** | **State when this occurred:** | | |
| Please indicate the reason (tick one) | During surgery | After surgery | During AND after surgery |
| Clinician decision | □ | □ | □ |
| Communication error | □ | □ | □ |
| Other (please specify): | □ | □ | □ |

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| **Other protocol deviation** |
| Other (please specify): |

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| **PROTOCOL DEVIATION** | |
| Briefly describe the protocol deviation | |
| Name and signature: | Date: |

**ONLY COMPLETE THIS FORM IF THE PARTICIPANT HAS PREMATURELY STOPPED THEIR PARTICIPATION IN THE TRIAL**

**IF A PARTICIPANT COULD NOT BE CONTACTED FOR FOLLOW-UP THEY ARE NOT AUTOMOMICALLY WITHDRAWN. ATTEMPTS SHOUD BE MADE TO FOLLOW-UP ALL PATIENTS, EVEN IF THEY MISS A VISIST / EVENT / FORM.**

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| **Date the patient prematurely discontinued study participation:** | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  **(DD-MMM-YYYY)** |
| **What was the primary reason for the discontinuation of the study?** | □ Withdrawn by clinician (please give reason)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ Patient withdrawal  □ Adverse event related  □ Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **In the case of patient withdrawal, please check:** | □ The participant agrees that any data collected up to the date of withdrawal can still be used  □ The patient would like their data removed from the database |

**ONLY COMPLETE THIS FORM IF THE PATIENT EXPERIENCED A SERIOUS ADVERSE EVENT**

***In the case of multiple serious adverse events, please complete a separate form for each one.***

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| --- | --- | --- | --- | --- |
| **SERIOUS ADVERSE EVENT FORM** | | | **YES** | **NO** |
| Did the patient experience a serious adverse event ***related*** to OPTIMISE II trial procedures? | | | □ | □ |
| If YES, please answer the following questions. | | | | |
| Date and time of onset of adverse event | |\_\_|\_\_|**/**|\_\_|\_\_|\_\_|**/**|\_\_|\_\_|\_\_|\_\_|  **(DD/MMM/YYYY)** | | |\_\_|\_\_|**:**|\_\_|\_\_|  **(HR:MINS)** | |
| Date study team aware of the event: | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  (DD/MMM/YYYY) | |  | |
| **Outcome of serious adverse event** | | | **YES** | **NO** |
| Death | | | □ | □ |
| Life-threatening complication | | | □ | □ |
| Prolonged hospital stay | | | □ | □ |
| Significant disability or incapacity | | | □ | □ |
| If YES to any option above, please notify the OPTIMISE II trial coordinating centre within 24 hours by email with a copy of this form: | | | | |
| **SERIOUS ADVERSE EVENT DESCRIPTION** | | | | |
| Please describe the serious adverse event, including any treatment or medication required. | | | | |
| Name and signature of PI: | | Date:  |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  (DD/MMM/YYYY) | | |
| SAE event end date: | | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  (DD/MMM/YYYY) | | |
| Date reported to REC (If applicable): | | |\_\_|\_\_|/|\_\_|\_\_|\_\_|/|\_\_|\_\_|\_\_|\_\_|  (DD/MMM/YYYY) | | |