

# Post-Operative Morbidity-Exercise: pre-operative exercise biology and post-operative outcomes

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| <b>Submission date</b><br>08/03/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>27/04/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>12/04/2017       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

Observational cohort study of the immune, bioenergetic and microcirculatory response to cardiopulmonary exercise testing in healthy volunteers and non-cardiac surgical patients

**Acronym**

POM-E

**Study objectives**

Exercise-induced changes in immune, autonomic and cardiovascular physiology are predictive of post-operative morbidity independent of exercise capacity.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Outer South East London REC - South London REC Office (4), 29/12/2009, ref: 09/H0805/59

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Post-operative morbidity

**Interventions**

Visit 0 (baseline): screening for inclusion/exclusion criteria; informed consent; demographic data collection

Visit 1 (within 3 weeks): cardiopulmonary exercise test; blood samples, microvascular and cardiopulmonary data collected pre- and 60 minutes post-exercise

Visit 2 (post-operative day 2): blood samples, microvascular and cardiopulmonary data collected pre- and 60 minutes post-exercise

Visit 3 (post-operative day 3): morbidity documented

Visit 4 (post-operative day 5): morbidity documented

Visit 5 (post-operative day 8): morbidity documented

Visit 6 (post-operative day 15): morbidity documented

Visit 7 (day of discharge): length of stay recorded

**Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome(s)**

Morbidity on post-operative day 3

**Key secondary outcome(s)**

Immune, bioenergetic, microcirculatory and cellular correlates associated with development of post-operative morbidity and length of hospital stay

**Completion date**

01/09/2011

## Eligibility

**Key inclusion criteria**

Patients undergoing major elective major surgical procedures that are associated with a high incidence of post-operative morbidity (abdominal/oesophageal/hepatic resection/gynaecology /urological reconstructive surgery) and who meet the following criteria:

1. American Society of Anaesthesiologists (ASA) risk grade 3 - 4
2. Aged greater than 50 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Acute myocardial ischaemia (contraindication for inotropic support)
2. Acute arrhythmias (contraindication for inotropic support)
3. Pregnancy (lithium-based cardiac output monitoring device)
4. Patients receiving palliative treatment only

**Date of first enrolment**

29/03/2010

**Date of final enrolment**

01/09/2011

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Wolfson Institute for Biomedical Research**  
London  
United Kingdom  
WC1E 6BT

## **Sponsor information**

### **Organisation**

University College London Hospitals NHS Foundation Trust (UK)

### **ROR**

<https://ror.org/042fqyp44>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Academy of Medical Sciences/The Health Foundation (UK) - Clinician Scientist Award to Dr GL Ackland

### **Funder Name**

University College London Hospitals NHS Foundation Trust (UK) - Comprehensive Biomedical Research Centre

### **Funder Name**

University College London (UK) - Centre for Anaesthesia, Critical Care and Pain Medicine

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration

### **Study outputs**

| <b>Output type</b>                            | <b>Details</b>                | <b>Date created</b> | <b>Date added</b> | <b>Peer reviewed?</b> | <b>Patient-facing?</b> |
|---|-------------------------------|---------------------|-------------------|-----------------------|------------------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025          | 11/11/2025        | No                    | Yes                    |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025          | 11/11/2025        | No                    | Yes                    |