

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

<b>Submission date</b> 08/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/04/2017	<b>Condition category</b> 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

**Study website**  
<https://www.ucl.ac.uk/anaesthesia/trials>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Diagnostic

### **Participant information sheet**

Can be found at <https://www.ucl.ac.uk/anaesthesia/trials>

### **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 measure**

Morbidity on post-operative day 3

**Secondary outcome measures**

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

**Overall study start date**

29/03/2010

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

106

**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**

England

United Kingdom

**Study participating centre**

**Wolfson Institute for Biomedical Research**

London

United Kingdom

WC1E 6BT

## **Sponsor information**

**Organisation**

University College London Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Joint UCLH/UCL Biomedical Research Unit

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uclh.nhs.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**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration