

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

Submission date 08/03/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/04/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/04/2017	Condition category Surgery	☐ Individual participant data ☐ 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

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

Primary study design

Observational

Study design

Observational cohort study

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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes

