

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

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

1st Floor, Maples House

149 Tottenham Court Road

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England

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+44 (0)20 7380 6978

n.mcnally@ucl.ac.uk

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