ISRCTN76894700 https://doi.org/10.1186/ISRCTN76894700

# Post-operative oxygen delivery in patients undergoing major non-cardiac surgery to reduce morbidity

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 22/01/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 15/03/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/07/2021 | Surgery | |

**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**
UK NIHR CSP 22346

## Study information

**Scientific Title**

Prospective randomised controlled trial of post-operative optimisation of oxygen delivery in patients undergoing major non-cardiac surgery to reduce morbidity

## Acronym
POM-O

## Study objectives
Enhancing oxygen delivery to a pre-determined target immediately post-operatively reduces post-operative morbidity and length of hospital stay in high risk surgical patients.

## 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/H0805/58

## Study design
Two-centre randomised double-blind placebo-controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Post-operative morbidity

## Interventions
Patients randomised to undergo fluid with/without inotropic support (goal-directed therapy) to achieve pre-defined oxygen delivery target for 6 hours immediately post-operatively.

## Intervention Type
Procedure/Surgery

## Phase
Not Applicable

## Primary outcome(s)
Reduction in post-operative morbidity on day 3 post-operatively as defined by the Post-Operative Morbidity Survey (POMS)

## Key secondary outcome(s))
Measured pre-operatively and at 1, 2, 5 and 8 days post-operatively:
1. Immune, bioenergetic, microcirculatory and cellular correlates associated with development of post-operative morbidity
2. Length of hospital stay

## Completion date
01/03/2013

# 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 risk grade 3 - 4
2. Aged greater than 50 years, either sex
3. Greater than two risk factors defined by the Revised Cardiac Risk Index

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Concurrent lithium therapy (incompatible with cardiac output monitoring device)
2. Acute myocardial ischaemia (contraindication for inotropic support)
3. Acute arrhythmias (contraindication for inotropic support)
4. Pregnancy (lithium-based cardiac output monitoring device)
5. Patients receiving palliative treatment only

### Date of first enrolment
01/03/2010

### Date of final enrolment
01/03/2013

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Wolfson Institute for Biomedical Research**
London
United Kingdom
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# Sponsor information

### Organisation
University College London Hospitals NHS Trust (UK)

### ROR
https://ror.org/042fqyp44

# Funder(s)

### Funder type
Research organisation

### Funder Name
Academy of Medical Sciences/Health Foundation (UK) - Clinician Scientist award to Dr GL Ackland

### Funder Name
University College London Hospitals NHS Trust/University College London (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? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2015 | | Yes | No |
| Results article | sub-study results | 05/07/2021 | 12/07/2021 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |

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|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |