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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Secondary outcome measures
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

Overall study start date
01/03/2010

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

Age group
Adult

Sex
Both

Target number of participants
204

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
England

United Kingdom

Study participating centre
Wolfson Institute for Biomedical Research
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London Hospitals NHS 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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Sponsor type
Hospital/treatment centre

Website
http://www.ucl.ac.uk/joint-rd-unit

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

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

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