

Optimisation of peri-operative cardiovascular management to improve surgical outcome

Submission date 05/06/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/07/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/03/2020	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
N/A

Study information

Scientific Title
Optimisation of peri-operative cardiovascular management to improve surgical outcome: open randomised controlled multi-centre trial

Acronym

OPTIMISE

Study objectives

Current hypothesis as of 03/05/2012

To establish whether protocolised administration of intra-venous fluid, combined with low dose dopexamine infusion will reduce the number of patients who experience complications within 30 days following major surgery involving the gastrointestinal tract.

Previous hypothesis

To establish whether protocolised administration of intra-venous fluid, combined with low dose dopexamine infusion will increase the number of patients who survive to 28 days following major surgery involving the gastrointestinal tract.

On 03/05/2012 the following changes were made to the trial record:

1. The overall trial end date was changed from 31/08/2013 to 30/04/2013.
2. The target number of participants has been updated from 3600 to 734.

On 10/01/2013 the overall trial end date was changed from 30/04/2013 to 18/05/2013.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East London and The City Research Ethics Committee, 13/03/2009, ref: 09/H0703/23

Study design

Open randomised controlled multi-centre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative complications

Interventions

Current interventions as of 03/05/2012

The trial intervention period begins at induction of anaesthesia and continues until six hours after surgery is complete (maximum duration 24 hours). For patients in the treatment group, stroke volume will be measured by arterial waveform analysis and 250 ml intra-venous colloid fluid challenges will be administered to achieve sustained rise in stroke volume. Patients in the intervention group will also receive a fixed dose intra-venous infusion of dopexamine (0.5 µg/kg /min). Other decisions for intervention group patients will be taken by clinical staff. Control group patients will receive usual clinical care with all decisions taken by clinical staff. Patients will be followed up for 30-day morbidity and mortality and 180-day mortality.

Previous interventions

Sample size for primary outcome: 3600 patients. However, trial only currently funded to first

interim analysis and secondary outcome of the number of patients developing complications within 28 days of surgery (726 patients).

The trial intervention period begins at induction of anaesthesia and continues until six hours after surgery is complete (maximum duration 24 hours). For patients in the treatment group, stroke volume will be measured by arterial waveform analysis and 250 ml intra-venous colloid fluid challenges will be administered to achieve sustained rise in stroke volume. Patients in the intervention group will also receive a fixed dose intra-venous infusion of dopexamine (0.5 µg/kg /min). Other decisions for intervention group patients will be taken by clinical staff. Control group patients will receive usual clinical care with all decisions taken by clinical staff. Patients will be followed up for 28-day morbidity and mortality and 180-day mortality.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current primary outcome measure(s):

Difference in the number of patients developing post-operative complications or dying within 30 days following randomisation between study groups.

Previous primary outcome measure(s):

Difference in 28 days post-mortality between study groups.

Key secondary outcome(s)

Current secondary outcome measure (s) as of 03/05/2012:

1. Difference in the number of patients developing 30-day post-operative mortality between groups
2. Difference in morbidity identified with the Post-Operative Morbidity Survey (POMS) for patients still in hospital on day seven after surgery
3. Difference in the number of patients developing infectious complications within 30 days of surgery
4. Difference in duration of post-operative hospital stay
5. Difference in 30 day critical care free days
6. Difference in 180 day post-operative mortality
7. Difference in cost effectiveness
8. Difference in healthcare costs

Previous secondary outcome measure(s):

1. Difference in the number of patients developing post-operative complications within 28 days of surgery between groups
2. Difference in morbidity identified with the Post-Operative Morbidity Survey (POMS) for patients still in hospital on day seven after surgery
3. Difference in the number of patients developing infectious complications within 28 days of surgery
4. Difference in duration of post-operative hospital stay
5. Difference in 28 day critical care free days

6. Difference in 180 day post-operative mortality
7. Difference in cost effectiveness
8. Difference in healthcare costs

Completion date

18/05/2013

Eligibility

Key inclusion criteria

Adult patients undergoing major abdominal surgery involving the gastrointestinal tract which is expected to take longer than 90 minutes are eligible for recruitment provided they satisfy one of the following additional criteria:

1. Urgent or emergency surgery
2. Acute or chronic renal impairment
3. Diabetes mellitus
4. Aged 65 years and older, either sex
5. Presence of a risk factor for cardiac or respiratory disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

Current exclusion criteria as of 03/05/2012

1. Patients receiving palliative treatment only
2. Acute myocardial ischaemia at time of enrolment
3. Pulmonary oedema at time of enrolment
4. Moderate/severe thrombocytopenia (platelet count $<50 \times 10^9/l$)
5. Patients receiving monoamine oxidase inhibitors (MAOIs)
6. Pheochromocytoma
7. Severe left ventricular outlet obstruction, e.g. hypertrophic obstructive cardiomyopathy or severe aortic stenosis
8. Known hypersensitivity to dopexamine hydrochloride or disodium edenate
9. Pregnancy
10. Septic shock

Previous exclusion criteria

1. Patients receiving palliative treatment only
2. Acute myocardial ischaemia at time of enrolment
3. Pulmonary oedema at time of enrolment
4. Moderate/severe thrombocytopenia
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7. Severe left ventricular outlet obstruction, e.g. hypertrophic obstructive cardiomyopathy or severe aortic stenosis
8. Known hypersensitivity to dopexamine hydrochloride or disodium edenate
9. Pregnancy

Date of first enrolment

01/09/2009

Date of final enrolment

19/11/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Barts and The London School of Medicine and Dentistry

London

United Kingdom

E1 1BB

Sponsor information

Organisation

Barts and The London School of Medicine and Dentistry, Queen Mary's University of London (UK)

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Clinician Scientist Award (held by R Pearse)

Funder Name

Intensive Care National Audit and Research Centre

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	04/06/2014		Yes	No
Results article	results	07/03/2019	11/03/2019	Yes	No
Results article	substudy results	01/12/2019	22/10/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	analysis	07/03/2019	31/03/2020	Yes	No
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