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Optimisation of peri-operative cardiovascular management to improve surgical outcome

Submission date	Recruitment status
05/06/2009	No longer recruiting
Registration date	**Overall study status**
24/07/2009	Completed
Last Edited	**Condition category**
31/03/2020	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.icnarc.org

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Available from Contract Research Organisation (CRO): http://www.icnarc.org

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 collid 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 collid 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 measure
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.

Secondary outcome measures
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

Overall study start date
01/09/2009

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

Age group
Senior

Sex
Both

Target number of participants
734 patients

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 thromocytopenia (platelet count <50 x 109/l)
5. Patients receiving monoamine oxidase inhibitors (MAOIs)
6. Phaechromocytoma
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
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9. Pregnancy

Date of first enrolment
01/09/2009

Date of final enrolment
19/11/2012

Locations

Countries of recruitment
England

United Kingdom

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)

Sponsor details
Joint R&D Office
24 - 26 Walden Street
London
England
United Kingdom
E1 2AN

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.uk/research

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

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	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
Other publications	analysis	07/03/2019	31/03/2020	Yes	No
HRA research summary			28/06/2023	No	No