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Physiological effects of goal directed therapy (incorportating dopexamine infusion) in patients undergoing major surgery

Submission date 04/10/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/01/2007	**Overall study status** Completed	
Last Edited 12/08/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R&D ref: 004670

Study information

Scientific Title

Study objectives
To assess whether post-operative Goal Directed Therapy results in improved clinical outcomes through enhanced tissue perfusion and oxygenation.

Please note that as of 23/10/2007 this application was amended. The amendment will allow us to compare the effects on tissue perfusion and oxygenation of post-operative Goal Directed Therapy with intravenous fluid alone and that of Goal Directed Therapy with fluid plus dopexamine. All changes relating to these amendments will be noted under the date '23/10 /2007'. These amendments have included the addition of two funders, a change to the target number of participants (as of 17/04/2007 this was updated to 80, and was originally entered as 120), a change to the anticipated start date (this was originally 01/12/2006) and an addition to the interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the London Multi-Centre Research Ethics Committee on the 17th November 2006 (ref: 06/MRE02/70).

Study design
Randomised single centre, single blind, study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Major abdominal surgery

Interventions

In addition to maintenance fluid, control group patients will receive additional 250 ml fluid challenges with colloid solution as required, to achieve a sustained rise in central venous pressure.

In addition to maintenance fluid, intervention group patients will receive additional 250 ml fluid challenges with colloid solution as required, to achieve a sustained rise in stroke volume. Patients in the intervention group will also receive dopexamine at a fixed rate of 0.5 mcg/kg/min.

As of 17/04/2007:
Due to funding problems we will only be able to recruit enough patients for our secondary outcome measure therefore only 80 participants are expected to be recruited.

As of 23/10/2007:
A second intervention group will receive, in addition to maintenance fluid, additional 250 ml fluid challenges with colloid solution as required, to achieve a sustained rise in stroke volume but this will not be supplemented with dopexamine.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Reduction in post-operative complication rates associated with the use of Goal Directed Therapy.

Added as of 23/10/2007:
Increase in tissue oxygenation associated with the use of Goal Directed Therapy.

Secondary outcome measures
1. Reduction in microvascular perfusion associated with the use of Goal Directed Therapy
2. Reduction in tissue oxygenation associated with the use of Goal Directed Therapy
3. Reduction in post-operative duration of hospital stay associated with the use of Goal Directed Therapy
4. Reduction in post-operative mortality associated with the use of Goal Directed Therapy

Overall study start date
01/11/2007

Completion date
01/12/2009

Eligibility

Key inclusion criteria
All adult patients admitted to intensive care or high dependency unit following elective major abdominal surgery

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
135 (45 per group) (added 23/10/2007)

Key exclusion criteria
1. Refusal of consent
2. Concurrent lithium therapy
3. Acute myocardial ischaemia
4. Acute arrhythmias
5. Pregnancy
6. Patients receiving palliative treatment only
7. Weight less than 40 kg

Date of first enrolment
01/11/2007

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
5th floor
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Queen Mary's University of London (UK)

Sponsor details
Joint R&D Office
3rd Floor Rutland House

42–46 New Road
Whitechapel
London
England
United Kingdom
E1 2AX

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
In decreasing order of size:

Funder Name
Circassia Ltd (UK) - research grant (added 23/10/2007)

Funder Name
Barts and the London Charity (UK) - research grant (added 23/10/2007)

Funder Name
Unrestricted educational grant: Zeneus Pharma Ltd (UK)

Funder Name
Unrestricted educational grant: LiDCO Ltd (UK)

Funder Name

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	01/01/2010		Yes	No