

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 04/10/2006 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/01/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 12/08/2010 | Condition category Surgery | <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
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

5th floor

London

United Kingdom

EC1A 7BE

Sponsor information

Organisation

Queen Mary's University of London (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

European Society of Intensive Care Medicine Intelligent Monitoring Award (Europe)

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 | 01/01/2010 | | Yes | No |