

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

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

**Primary study design**

Interventional

**Study design**

Randomised single centre, single blind, study.

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/01/2010   |            | Yes            | No              |