

# Early goal directed therapy following major surgery reduces complications and duration of hospital stay: a randomised, controlled trial

<b>Submission date</b> 10/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/02/2008	<b>Condition category</b> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

### Scientific Title

### Study objectives

That post-operative goal directed therapy reduces the incidence of complications following major general surgery

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration.

### Study design

Randomised controlled trial

### 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 general surgery

### Interventions

Goal directed therapy protocol to achieve oxygen delivery index of 600 ml/min/m<sup>2</sup> compared to protocol designed to reflect standard care.

### Intervention Type

Procedure/Surgery

### Phase

Not Specified

### Primary outcome measure

Incidence of post-operative complications.

## Secondary outcome measures

Mortality and duration of hospital stay.

## Overall study start date

01/11/2002

## Completion date

01/08/2004

# Eligibility

## Key inclusion criteria

Patients aged 18 years or older presenting for major surgery expected to last more than one and a half hours were eligible for inclusion if one or more of the following criteria were satisfied before surgery:

1. Severe cardiac or respiratory illness resulting in severe functional limitation
2. Extensive surgery planned for carcinoma involving bowel anastomosis
3. Acute massive blood loss (greater than 2.5 l)
4. Aged over 70 years with moderate functional limitation of one or more organ systems
5. Septicaemia (positive blood cultures or septic focus)
6. Respiratory failure (partial pressure of oxygen in arterial blood [PaO<sub>2</sub>] less than 8 kPa on Fraction of inspired Oxygen [FiO<sub>2</sub>] greater than 0.4, i.e., PaO<sub>2</sub> : FiO<sub>2</sub> ratio less than 20 kPa or ventilation greater than 48 hours)
7. Acute abdominal catastrophe (e.g., pancreatitis, perforated viscous, gastro-intestinal bleed)
8. Acute renal failure (urea greater than or equal to 20 mmol/l, creatinine greater than 60 µmol/l)
9. Surgery for abdominal aortic aneurysm

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

300

## Key exclusion criteria

1. Refusal of consent
2. Pregnancy
3. Acute myocardial ischaemia prior to enrolment
4. Patients receiving palliative treatment only
5. Disseminated malignancy
6. Patients unlikely to survive more than 6 hours
7. Patients requiring intervention outside intensive care unit (ICU) within the first 6 hours

following surgery  
8. Patients on lithium therapy  
9. Weight less than 40 kg

**Date of first enrolment**

01/11/2002

**Date of final enrolment**

01/08/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Intensive Care Unit**

London

United Kingdom

SW170QT

## **Sponsor information**

**Organisation**

St Georges Hospital (UK)

**Sponsor details**

Blackshaw Road

London

England

United Kingdom

SW17 0QT

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/0001ke483>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

The Intensive Care Research Fund managed by the St Georges Hospital charitable funds trustees (UK)

## 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?
<a href="#">Results article</a>	Results	01/12/2005		Yes	No