

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

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

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major general surgery

Interventions

Goal directed therapy protocol to achieve oxygen delivery index of 600 ml/min/m² compared to protocol designed to reflect standard care.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Incidence of post-operative complications.

Key secondary outcome(s)

Mortality and duration of hospital stay.

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 [PaO₂] less than 8 kPa on Fraction of inspired Oxygen [FiO₂] greater than 0.4, i.e., PaO₂ : FiO₂ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

Intensive Care Unit

London
United Kingdom
SW170QT

Sponsor information

Organisation

St Georges Hospital (UK)

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

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	01/12/2005		Yes	No