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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
10/09/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/09/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/02/2008	Surgerv			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Rupert Pearse

#### Contact details

Intensive Care Unit
1st Floor St James' Wing
St George's Hospital
London
United Kingdom
SW170QT
+44 (0)7718 910 440
rupert.pearse@doctors.net.uk

# Additional identifiers

**Protocol serial number** 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

#### 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/m^2 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 anastamosis
- 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