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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

Registration date
28/09/2005

Overall study status
Completed

Last Edited
19/02/2008

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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.

Primary study design
Interventional

Study design
Randomised controlled trial

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