

Would continued ventilation during cardiopulmonary bypass reduce lung complications following cardiac surgery?

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/07/2009	Condition category Surgery	☐ 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
N0116135566

Study information

Scientific Title

Study objectives

Does continued ventilation during cardiopulmonary bypass reduce lung complications following cardiac 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

Surgery: Cardiovascular

Interventions

In order to answer the research question above the study has the following specific research aims. For selected patients undergoing cardiac surgery and randomised into either a group that is ventilated on bypass or a group that is not, to measure and compare between the two groups:

1. Pulmonary gas exchange
2. Lung mechanics
3. The activation of "inflammatory" pathways within the lungs
4. The presence of increased pulmonary vascular endothelial permeability
5. The presence of other evidence for pulmonary vascular endothelial damage or lung epithelial injury

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

1. intubation time
2. duration of inpatient stay
3. incidence of chest complications

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/08/2004

Eligibility

Key inclusion criteria

1. male
2. aged between 50-75 years
3. normal or mildly impaired left ventricular function and no significant elevation of pulmonary artery pressure on preoperative echocardiogram
4. body mass index <30

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Male

Key exclusion criteria

1. insulin dependent diabetes
2. history of lung disease

Date of first enrolment

01/09/2003

Date of final enrolment

01/08/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cardiothoracic Surgery

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Other

Funder Name

Kings College Hospital NHS Trust R&D Consortium (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	01/02/2008		Yes	No