ISRCTN25577630 https://doi.org/10.1186/ISRCTN25577630

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 21/07/2009	**Condition category** Surgery	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

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

Age group
Other

Sex
Male

Target number of participants
23

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
England

United Kingdom

Study participating centre
Cardiothoracic Surgery
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Other

Funder Name
Kings College Hospital NHS Trust R&D Consortium (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?
Results article	results	01/02/2008		Yes	No