ISRCTN75795633 https://doi.org/10.1186/ISRCTN75795633

To investigate whether during cardiac surgery with cardiopulmonary bypass the lungs are better protected from injury if they receive low frequency ventilation.

Submission date 09/06/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/06/2010	**Overall study status** Completed	
Last Edited 30/09/2024	**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

CS/2009/3259

Study information

Scientific Title
Pulmonary protection with low frequency ventilation during cardiac surgery with cardiopulmonary bypass: a randomised controlled trial

Acronym
PROTECTION 1

Study objectives
During conventional open-heart surgery the heart is stopped, most of the blood supply is diverted from the heart and lungs to the heart-lung machine (known as cardiopulmonary bypass) and the lungs are disconnected from the ventilator and left open to air. Cardiopulmonary bypass is known to be associated with major injury to the heart and lungs. The hypothesis for this study is that ventilating the lungs at low frequency rate will prevent significant injury to the lungs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre parallel-group open randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information leaflet

Health condition(s) or problem(s) studied
Coronary artery and or valvular disease

Interventions

Control group: during cardiopulmonary bypass the lungs will be disconnected from ventilator and left open to air (i.e. usual care).
Intervention group: during cardiopulmonary bypass the lungs will be ventilated at low frequency rate (5/min with air (21% oxygen) at a tidal volume of 6-8 ml/Kg).

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Release of inflammatory mediators:
1. Thromboxane A2
2. TNFα
3. IL-1β
4. IL-6
5. IL-10
Measured in plasma samples taken at post-induction and pre-sternotomy, 10 minutes following CPB weaning, and 2, 6, 12, and 24 hours post CPB weaning.

Secondary outcome measures
1. Measurement of oxidative stress from left atrial and right atrial blood sampling post-cannulation, before institution of CPB and on weaning from CPB
2. Pulmonary function tests carried out before surgery, at hospital discharge, and at 6-8 weeks post surgery
3. Pulmonary gas exchange measured post-induction and pre-sternotomy, 10 minutes following CPB weaning, 2 and 6 hours post CPB weaning
4. Respiratory system and lung mechanics measured on arrival on ICU, 2 and 6 hors post CPB weaning
5. Intrapulmonary shunt fraction measured post-induction and pre-sternotomy, 10 minutes following CPB weaning, and before chest closure
6. Pulmonary trapping of white blood cells measured post-cannulation, before institution of CPB and on weaning from CPB
7. A composite endpoint of lung-related complications
8. The time until patients are classified as fit for discharge

Overall study start date
01/09/2010

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Age >16 and <80 years
2. Undergoing any elective or urgent coronary artery bypass grafting (CABG) with >3 grafts,

valve, or CABG+Valve adult cardiac surgery procedure with cardiopulmonary bypass and cardioplegic arrest
3. Left ventricular ejection fraction > 25%

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
60

Total final enrolment
63

Key exclusion criteria
1. Previous pulmonary embolism requiring long term warfarin for > 3 months
2. Previous cardiac surgery
3. Current congestive heart failure (NYHA class IV)/cardiogenic shock
4. Chronic renal failure requiring dialysis
5. Emergency or salvage operation
6. On corticosteroid or immunosuppressive treatment

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Heart Institute
Level 7

Bristol Royal Infirmary
Bristol
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BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Research and Development Department
Education Centre Level 3
Upper Maudlin Street
Bristol
England
United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

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		30/09/2024	30/09/2024	Yes	No