

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	☒ Prospectively registered ☐ Protocol
Registration date 16/06/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/09/2024	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Raimondo Ascione

Contact details
Bristol Heart Institute
Level 7
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Single-centre parallel-group open randomized controlled trial

Study type(s)

Treatment

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(s)

Release of inflammatory mediators:

1. Thromboxane A2
2. TNF α
3. IL-1 β
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.

Key secondary outcome(s)

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 hours 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 Years

Upper age limit

80 Years

Sex

All

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**

United Kingdom

England

Study participating centre**Bristol Heart Institute**

Level 7

Bristol Royal Infirmary

Bristol

United Kingdom

BS2 8HW

Sponsor information**Organisation**

University Hospitals Bristol NHS Foundation Trust

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

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