

The influence of surgical interventions with and without cardiopulmonary bypass on Ca²⁺ signalling in alveolar macrophages

Submission date 26/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2007	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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10117

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

VO 741/6-1

Study information

Scientific Title

Acronym

Cacao

Study objectives

A direct G-protein-stimulated ratiometric calcium ion (Ca^{2+}) signal in alveolar macrophages decreases after surgical interventions with cardiopulmonary bypass.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Charite - Universitaetsmedizin Berlin ethikkommission on the 8th March 2003 (ref: EA1/146/06).

Study design

Prospective cohort trial with two control groups.

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pulmonary dysfunction after surgery

Interventions

Bronchoscopy with Broncho-Alveolar Lavage (BAL) and blood samples before and after surgery. Routine bronchoscopy is used as recommended in a guideline. Duration of treatment is defined by the length of hospital stay. Duration of the diagnostic procedure is approximately 10 minutes. Total duration of follow up also is defined by the length of the hospital stay.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Calcium signal intensity, measured immediately preoperatively and after the surgical procedure.

Secondary outcome measures

Postoperative pulmonary infection, measured on day of discharge.

Overall study start date

01/06/2007

Completion date

31/05/2010

Eligibility**Key inclusion criteria**

1. Elective coronary bypass graft surgery
2. Elective panendoscopy
3. Elective thoracic surgery

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Aged less than 18 years
2. Relevant pulmonary diseases with oxygenation deficit
3. Liver disease stage greater than Child B
4. Human Immunodeficiency Virus (HIV)-infection
5. Corticosteroid therapy
6. Organ transplantation
7. Perioperative infection
8. Chronic inflammatory disease
9. Pregnancy

Date of first enrolment

01/06/2007

Date of final enrolment

31/05/2010

Locations

Countries of recruitment

Germany

Study participating centre

Klinik für Anaesthesiologie und Operative Intensivmedizin

Berlin

Germany

10117

Sponsor information**Organisation**

Charite - University Medicine Berlin (Charite - Universitaetsmedizin Berlin) (Germany)

Sponsor details

Chariteplatz 1

Berlin

Germany

10117

Sponsor type

University/education

Website

<http://www.charite.de>

ROR

<https://ror.org/001w7jn25>

Funder(s)**Funder type**

University/education

Funder Name

Humboldt University of Berlin (Germany)

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