ISRCTN94348100 https://doi.org/10.1186/ISRCTN94348100

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	[_] Prospectively registered [_] Protocol
Registration date 06/11/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/11/2007	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

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
VO 741/6-1

Study information

Scientific Title

Acronym
Cacao

Study objectives
A direct G-protein-stimulated ratiometric calcium ion (Ca2+) 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 fur 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