The impact of a hematocrit of 20% during normothermic cardiopulmonary bypass for elective coronary artery bypass graft surgery on oxygen delivery and clinical outcome: a randomised controlled study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/01/2006		Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/01/2006	Completed	[X] Results		
Last Edited 29/03/2010	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Claudia Spies

Contact details

Dept. of Anesthesiology and Intensive Care Medicine Charite-University Hospital Berlin Schumannstr. 20-21 Berlin Germany 10098 +49 (0)3045 053 1012 claudia.spies@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

krit hematocrit study

Study objectives

To evaluate whether a hematocrit of 20% versus 25% during normothermic cardiopulmonary bypass for Coronary Artery Bypass Graft (CABG) surgery influences oxygen delivery and oxygen consumption.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Coronary artery disease requiring surgical revascularisation

Interventions

Hemodilution during cardiopulmonary bypass achieving a hematocrit of 20% versus 25%.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Oxygen delivery and oxygen consumption.

Secondary outcome measures

- 1. Myocardial infarction
- 2. Renal insufficiency measured as creatinine and urine volume
- 3. Neurological deficits displayed as agitated arousal reactions and stroke

Overall study start date

01/02/2004

Completion date

31/01/2005

Eligibility

Key inclusion criteria

Coronary artery disease patients to about to undergo coronary artery bypass graft surgery.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

- 1. Ejection fraction less than 40%
- 2. Chronic Obstructive Pulmonary Disease (COPD)
- 3. Renal insufficiency
- 4. Peripheral artery disease
- 5. Hepatic dysfunction

Date of first enrolment

01/02/2004

Date of final enrolment

31/01/2005

Locations

Countries of recruitment

Study participating centre

Dept. of Anesthesiology and Intensive Care Medicine

Berlin

Germany
10098

Sponsor information

Organisation

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details

Department of Anesthesiology and Intensive Care Medicine Schumannstr. 20-21 Berlin Germany 10098 +49 (0)3045 053 1012 anaesth@charite.de

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/001w7jn25

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany) - institutional funding

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	01/07/2006		Yes	No
Results article	results	01/07/2009		Yes	No