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

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
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

Germany

Study participating centre
Dept. of Anesthesiology and Intensive Care Medicine
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Sponsor information

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

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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