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The effect of brain temperature on neuropsychological outcome following cardiopulmonary bypass

Submission date
15/10/2004

Recruitment status
No longer recruiting

Registration date
23/06/2005

Overall study status
Completed

Last Edited
10/11/2010

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
MCT-38146

Study information

Scientific Title
The effect of brain temperature on neuropsychological outcome following cardiopulmonary bypass: a single centre, two arm, randomised parallel trial

Acronym
NPSYCH2

Study objectives
Maintaining mild hypothermia (34°C) compared to normothermia (37°C) throughout the entire intra-operative period will decrease brain injury during coronary artery surgery with cardiopulmonary bypass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Board, University of Ottawa Heart Institute, Ottawa, Ontario (Canada) approved on the 27th April 2004 (ref: #UOHI 00-113)

Study design
Single centre, two arm, randomised parallel trial with study participant and investigator, outcome assessor, and data analyst blinded

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Cognitive deficits following cardiopulmonary bypass

Interventions
Randomisation to maintenance of body and brain temperature constant at 34 °C or 37 °C during the entire intra-operative period. Eleven tests were combined into three cognitive domains:
1. Memory
2. Attention
3. Psychomotor speed and dexterity

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
The incidence of cognitive deficits at 5 - 7 days after surgery.

Secondary outcome measures
1. Incidence of cerebral emboli during cardiopulmonary bypass (CPB) as measured by trans-cranial doppler
2. Quality of life at 3 months and the incidence of cognitive deficits at 3 months

Overall study start date
01/08/1995

Completion date
01/02/1998

Eligibility

Key inclusion criteria
Male or female 60 years or older undergoing coronary artery surgery utilising cardiopulmonary bypass.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
334

Key exclusion criteria
1. Emergency surgery
2. Unable to undergo cognitive testing (visual or motor problems, unable to speak French or English)
3. Mini Mental State Examination (MMSE) less than 24 (dementia)
4. Patients undergoing other cardiac procedures in addition to coronary artery bypass graft (CABG) or reoperation
5. Patients with Parkinson's disease or a history of stroke
6. Age less than 60
7. Patients with renal insufficiency (creatinine 2 x normal) or hepatic insufficiency

Date of first enrolment
01/08/1995

Date of final enrolment
01/02/1998

Locations

Countries of recruitment
Canada

Study participating centre
Ottawa Heart Institute
Ottawa
Canada
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Sponsor information

Organisation
University of Ottawa Heart Institute (Canada)

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Sponsor type
University/education

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-38146)

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	neuroprotective effect results	18/09/2001		Yes	No
Results article	five-year follow-up results	01/05/2007		Yes	No
Results article	neurocognitive function results:	01/12/2007		Yes	No
Results article	renal function results	01/02/2009		Yes	No
Results article	cognitive dysfunction results	01/10/2010		Yes	No