# The effect of brain temperature on neuropsychological outcome following cardiopulmonary bypass

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
15/10/2004		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
23/06/2005		[X] Results		
Last Edited		Individual participant data		
10/11/2010	Injury, Occupational Diseases, Poisoning			

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Howard Nathan

#### Contact details

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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 transcranial 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 K1Y 4W7

# Sponsor information

#### Organisation

University of Ottawa Heart Institute (Canada)

#### Sponsor details

40 Ruskin St H341 Ottawa Canada K1Y 4W7 +1 613 761 4775 hnathan@ottawaheart.ca

#### 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