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PRO-TECT II: Propofol cardioprotection for type II diabetics

Submission date	Recruitment status	[_] Prospectively registered
05/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2016	Nutritional, Metabolic, Endocrine	

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
NCT00734383

Secondary identifying numbers

210938

Study information

Scientific Title
Propofol cardioprotection during ischaemia-reperfusion to preserve myocardial function: an interventional randomised efficacy study

Acronym
PRO-TECT II

Study objectives
Elevated oxidant stress may occur during myocardial ischaemia-reperfusion, influencing release and action of tumour necrosis factor-alpha (TNF-a), which inhibits cardioprotective endothelial NOS (eNOS), enhances endothelin-1 (ET-1) formation, and promotes the conversion of nitric oxide to cardiotoxic peroxynitrite. These factors cause cardiac dysfunction. Effective antioxidant intervention during ischaemia-reperfusion will preserve myocardial function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of British Columbia (UBC) Clinical Research Ethics Board, 22/09/2009, ref: H04-70456

Study design
Interventional treatment randomised double-blind (subject, investigator) placebo-controlled parallel assignment efficacy study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardioprotection for type II diabetics

Interventions
1. Experimental - propofol cardioprotection:
Ten minutes prior to initiation of CPB, we will stop delivery of isoflurane, inject 1 mg/kg

intravenous (iv) and then continuously infuse propofol at 120 µg/kg/min iv until 15 minutes after release of the aortic cross clamp (reperfusion).

2. Experimental - volatile anaesthesia preconditioning:
Anaesthesia will be maintained using an inspired concentration of isoflurane between 0.5 - 2% before, during, and after CPB, without administration of propofol. For ten minutes prior to the initiation of CPB we will deliver Isoflurane 2.5% end tidal then resume maintenance anaesthesia as described.

Total duration of treatment and follow up is currently up to 30 days post-operatively at the current time.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Propofol

Primary outcome measure
Peri-operative plasma 15 f2t isoprostane, a biologically active marker of oxidative stress.
Timeframe: 24 hours post-operation.

Secondary outcome measures
Biochemical outcomes:
1. Plasma total antioxidant concentration
2. Systemic and coronary sinus levels of troponin I, ET-1, TNF-a, and peroxynitrite formation in blood
3. Gene and protein expression of inducible NOS (iNOS) and eNOS
4. Protein expression of Akt and its activation
5. Evidence of superoxide formation in atrial tissue

Clinical outcomes:
6. Incidence rate of low cardiac output syndrome during the first 6 hours after surgery
7. Incidence rate of inotropic support or intra-aortic balloon counterpulsation required for greater than 30 minutes duration to treat low cardiac output syndrome
8. Intensive care unit and hospital lengths of stay

Overall study start date
01/04/2007

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Adult patients aged 18 - 80 years, either sex
2. Undergoing primary coronary artery bypass graft (CABG) surgery requiring cardiopulmonary

bypass (CPB) at the Vancouver General Hospital
3. Require revascularisation of three or more coronary arteries with an anticipated aortic cross-clamp time of at least 60 minutes
4. Have a pre-operative systolic blood pressure above 90 mmHg in the absence of inotropic or mechanical support

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
144 (study recruitment completed)

Key exclusion criteria
1. Type I diabetes mellitus (defined as an established history and diagnosis of diabetes mellitus requiring insulin therapy from the time of diagnosis)
2. Co-existing valvular heart disease (moderate to severe aortic stenosis or mitral regurgitation)
3. Acute or evolving myocardial infarction
4. History of hypersensitivity to propofol or any of its formulation components
5. Taking non-steroidal anti-inflammatory drugs, vitamin C, or vitamin E within five days of surgery

Date of first enrolment
01/04/2007

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Canada

Study participating centre
University of British Columbia
Vancouver
Canada
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Sponsor information

Organisation
University of British Columbia (Canada)

Sponsor details
Office of Research Services
#102 - 6190 Agronomy Road
Vancouver, British Columbia
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Sponsor type
University/education

Website
http://www.ors.ubc.ca/

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: 210938)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	01/04/2016		Yes	No