

Post-operative low molecular weight heparin bridging therapy versus placebo bridging therapy for patients who are at high risk for arterial thromboembolism

Submission date 04/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/04/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Joseph Kovacs

Contact details
Victoria Hospital
800 Commissioners Road East, Room A2-401
London, Ontario
Canada
N6A 4G5
+1 519 685 8475
michael.kovacs@lhsc.on.ca

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00432796

Protocol serial number
MCT-79607

Study information

Scientific Title

A double blind randomised controlled trial of post-operative low molecular weight heparin bridging therapy versus placebo bridging therapy for patients who are at high risk for arterial thromboembolism

Acronym

PERIOP2

Study objectives

Efficacy:

Omitting post-operative bridging therapy with low molecular weight heparin (LMWH) will reduce the risk of thromboembolic complications in patients with prosthetic heart valves or atrial fibrillation who are at high risk for arterial embolism when warfarin is temporarily interrupted.

Safety:

Omitting post-operative bridging therapy with LMWH will reduce the risk of bleeding complications in patients with prosthetic heart valves or atrial fibrillation who are at high risk for arterial embolism when warfarin is temporarily interrupted.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Research Ethics Board of the University of Western Ontario approved on the 12th September 2006 (ref: 12559)
2. Research Ethics Board of Ottawa Hospital, General Campus approved on the 20th October 2008 (ref: 2006513-01H)
3. Capital Health Research Ethics Board approved on the 27th September 2006 (ref: CDHA-RS /2006-247)
4. Hamilton Health Sciences Research Ethics Board approved on the 17th November 2006 (ref: 06-363)
5. McGill University Health Centre Research Ethics Board approved on the 2nd March 2007 (ref: 06-038)
6. SMBD-Jewish General Hospital Research Ethics Committee approved on the 4th October 2006 (ref: 06-078)
7. St. Paul's Hospital - Providence Health Care Research Institute approved on the 6th June 2007 (ref: H07-01391)
8. Toronto General Hospital - University Health Network Research Ethics Board approved on the 24th April 2008 (ref: 07-0788-A)

Study design

Multicentre, two arm, randomised parallel trial with study participant, study investigator, caregiver, and outcome assessor blinded

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Arterial thromboembolism

Interventions

Experimental:

1. Placebo 5,000 units subcutaneously once a day for four days post-operatively or until the International Normalised Ratio (INR) is greater than 2.0, or
2. Placebo 200 units subcutaneously once a day for four days post-operatively or until the INR is greater than 2.0

Control:

1. Dalteparin 5,000 units subcutaneously once a day for four days post-operatively or until the INR is greater than 2.0, or
2. Dalteparin 200 units subcutaneously once a day for four days post-operatively or until the INR is greater than 2.0

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dalteparin

Primary outcome(s)

Major thromboembolism including:

1. Ischaemic stroke
2. Symptomatic myocardial infarction
3. Peripheral embolism
4. Valve thrombosis
5. Venous thromboembolism
6. Vascular death

Outcomes will be measured at three months.

Key secondary outcome(s)

1. Minor thromboembolism
2. Major bleeding
3. Minor bleeding
4. Overall survival

Outcomes will be measured at three months.

Completion date

01/05/2011

Eligibility

Key inclusion criteria

1. Informed consent
2. Patients of either sex, 18 years and older, with prosthetic heart valves receiving long-term oral anticoagulation with warfarin, or
3. Patients with atrial fibrillation and a major risk factor (previous transient ischaemic attack (TIA) or stroke, high blood pressure, diabetes, 75 years and older, moderate/severe left ventricle dysfunction), who require elective non-cardiac surgery or an invasive procedure with reversal of their anticoagulant therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Evidence of active bleeding prior to stopping warfarin
2. Platelet count less than $100 \times 10^9/L$
3. Spinal or neurosurgery
4. Life expectancy less than three months
5. Serum creatinine greater than $150 \mu\text{mol/L}$
6. Patients requiring cardiac surgery
7. Multiple prosthetic valves or Starr-Edwards valves or prosthetic valves with a history of stroke or TIA

Date of first enrolment

01/05/2006

Date of final enrolment

01/05/2011

Locations**Countries of recruitment**

Canada

Study participating centre

Victoria Hospital
London, Ontario
Canada
N6A 4G5

Sponsor information

Organisation

London Health Sciences Centre (Canada)

ROR

<https://ror.org/037tz0e16>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-79607)

Funder Name

Pfizer Canada Inc. (Canada) - medication only

Results and Publications

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	29/11/2018	19/02/2019	Yes	No