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

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|---|---|---|
| **Submission date**<br>04/06/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>04/06/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>11/04/2019 | **Condition category**<br>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**
NCT00432796

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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.

## Secondary outcome measures

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

Outcomes will be measured at three months.

### Overall study start date
01/05/2006

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
1773

### Key exclusion criteria
1. Evidence of active bleeding prior to stopping warfarin
2. Platelet count less than 100 x 10^9/L
3. Spinal or neurosurgery
4. Life expectancy less than three months
5. Serum creatinine greater than 150 umol/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**
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# Sponsor information

**Organisation**
London Health Sciences Centre (Canada)

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**Sponsor type**
Research organisation

**Website**
http://www.lhsc.on.ca/

**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

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