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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

Submission date
04/06/2008

Registration date
04/06/2008

Last Edited
11/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] 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

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 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
London, Ontario
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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