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Extended Prophylaxis Comparing low molecular weight heparin (LMWH) to Aspirin in Total hip arthroplasty

Submission date 27/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/09/2007	**Overall study status** Completed	
Last Edited 05/08/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
MCT-82948

Study information

Scientific Title

Acronym
EPCAT

Study objectives
Current hypothesis as of 05/12/2007:
Extending the duration of anti-thrombotic prophylaxis with aspirin by 28 days following a ten day course of Low Molecular Weight Heparin (LMWH) will be as effective at reducing the rate of symptomatic venous thromboembolic complications and will be safe and more cost-effective than extending prophylaxis by 28 days with LMWH in a group of patients undergoing total hip arthroplasty.

Previous hypothesis:
Extending the duration of anti-thrombotic prophylaxis with aspirin by 28 days following a minimum seven day course of Low Molecular Weight Heparin (LMWH) will be as effective at reducing the rate of symptomatic venous thromboembolic complications and will be safe and more cost-effective than extending prophylaxis by 28 days with LMWH in a group of patients undergoing total hip arthroplasty.

Please note that this record has been updated on the 5th December 2007 due to changes made to this protocol by the suggestion of the Research Ethics Board (REB). All changes were made prior to the recruitment of the first study participant and will be entered in this record under the date 05/12/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of Capital District Health Authority, Halifax, Nova Scotia, Canada approved on the 17th September 2007 (ref: CDHA-RS/2007-179)

Primary study design
Interventional

Study design
Multicentre, two arm, randomised parallel trial, using placebo, with study participant, research coordinator, study investigator, caregiver, outcome assessor, and data analyst blinded

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Venous thromboembolism following total hip arthoplasty

Interventions
Current interventions as of 05/12/2007:
1. Aspirin: 81 mg once a day for 28 days
2. Dalteparin: 5000 i.u. subcutaneously once a day
3. Matching placebo (aspirin): one pill once a day for 28 days
4. Matching placebo (dalteparin-normal saline): injection subcutaneously once a day for 28 days

Previous interventions:
1. Aspirin: 81 mg once a day for 28 days
2. Enoxaparin: 40 mg subcutaneously once a day for 28 days
3. Matching placebo (aspirin): one pill once a day for 28 days
4. Matching placebo (enoxaparin): injection subcutaneously once a day for 28 days

Contact for public queries:
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Aspirin, dalteparin

Primary outcome(s)
Current primary outcome measures as of 15/01/2008:
Venous thromboembolism (pulmonary embolism of deep vein thrombosis), assessed at 90 days.

Previous primary outcome measures:
1. Symptomatic venous thromboembolic complications, assessed at 90 days
2. Venous thromboembolism (pulmonary embolism of deep vein thrombosis), assessed at 90 days

Key secondary outcome(s)
Current secondary outcome measures as of 15/01/2008:
1. Survival, assessed at 90 days
2. Major bleeding, assessed at 90 days
3. Wound infection, assessed at 90 days
4. Stroke, assessed at 90 days
5. Thrombocytopenia, assessed at 90 days
6. Cost effectiveness, assessed at 90 days

Previous secondary outcome measures:
1. Survival, assessed at 90 days
2. Major bleeding, assessed at 90 days
3. Myocardial infarction, assessed at 90 days
4. Stroke, assessed at 90 days
5. Cost effectiveness, assessed at 90 days

Completion date
30/03/2011

Eligibility

Key inclusion criteria
1. Patients undergoing elective total hip arthroplasty at the participating institutions
2. Age 18 years and older, either sex. However, please note that if a patient under 18 years presents to the clinic (although this is unlikely), they will be included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Added as of 25/02/2009:
15. Investigator decision
16. Bilateral total hip arthroplasty (THA) or simultaneous hip and knee surgery
17. Unable to give consent
18. Geographical inaccessibility
19. Requirement for major surgery within 28 day study-drug period

Amended as of 05/12/2007:
1. Hip fracture in the previous three months
2. Metastatic cancer
3. Life expectancy less than 6 months
4. History of major bleeding that, in the judgement of the investigator, precludes use of anticoagulant prophylaxis
5. History of aspirin allergy, active peptic ulcer disease or gastritis that, in the judgment of the investigator, precludes use of aspirin
6. History of heparin induced thrombocytopenia or heparin allergy
7. Creatine clearance less than 30 ml per minute
8. Platelet count less than 100 x 10^9/L
9. Need for long-term anticoagulation due to pre-existing co-morbid conditions or due to the development of venous thromboembolism following surgery but prior to randomisation
10. Need for aspirin over the course of the study due to pre-existing co-morbid condition
11. Previous participation in this study
12. Refusal to give informed consent
13. Did not, or will not, receive dalteparin post-operatively for Venous Thromboembolism (VTE)

prophylaxis
14. Women of child bearing potential who are not abstinent or do not use appropriate contraception throughout the study drug period

Initial information at time of registration:
1. Hip fracture in the previous three months
2. Metastatic cancer
3. Life expectancy less than 6 months
4. History of major bleeding that, in the judgement of the investigator, precludes use of anticoagulant prophylaxis
5. History of aspirin allergy, active peptic ulcer disease or gastritis that, in the judgment of the investigator, precludes use of aspirin
6. History of heparin induced thrombocytopenia or heparin allergy
7. Chonic renal failure (creatine clearance less than 30 ml per minute)
8. Platelet count less than 100 x 10^9/L
9. Need for long-term anticoagulation due to pre-existing co-morbid conditions or due to the development of venous thromboembolism following surgery but prior to randomisation
10. Need for aspirin over the course of the study due to pre-existing co-morbid condition
11. Previous participation in this study
12. Geographic inaccessibility for follow-up
13. Refusal to give informed consent

Date of first enrolment
01/09/2007

Date of final enrolment
30/03/2011

Locations

Countries of recruitment
Canada

Study participating centre
Queen Elizabeth II (QEII) Health Sciences Centre and Dalhousie University
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Sponsor information

Organisation
Dalhousie University (Canada) - Research Services

ROR
https://ror.org/01e6qks80

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr.irsc.gc.ca (ref: MCT-82948)

Funder Name
Bayer Healthcare (Canada)

Alternative Name(s)
BHC

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Funder Name
Pfizer (Canada) - added 05/12/2007

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	04/06/2013		Yes	No