

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

<b>Submission date</b> 27/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/08/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

**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)

## **Study design**

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

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Venous thromboembolism following total hip arthroplasty

## **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  $100 \times 10^9/L$
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. Chronic renal failure (creatinine clearance less than 30 ml per minute)
8. Platelet count less than  $100 \times 10^9/L$
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**

Halifax, Nova Scotia

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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?
<a href="#">Results article</a>	results	04/06/2013		Yes	No