

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

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

Contact details
Queen Elizabeth II (QEII) Health Sciences Centre and Dalhousie University
Room 430 Bethune Building, 4th floor
1278 Tower Road
Halifax, Nova Scotia
Canada
B3H 2Y9
+1 902 473 8562
David.Anderson@cdha.nshealth.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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:

Susan Pleasance, Associate Director

Haematology Research

Centre for Clinical Research

5790 University Avenue, Room 132

Halifax, Nova Scotia

B3H 1V7

Canada

Tel: +1 902 473 7585

Fax: +1 902 473 4667

Email: Susan.Pleasance@cdha.nshealth.ca

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Aspirin, dalteparin

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/09/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

2200 (2222 as of 05/12/2007)

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

Canada

B3H 2Y9

Sponsor information

Organisation

Dalhousie University (Canada) - Research Services

Sponsor details

Room 321, Henry Hicks Academic Administration Building

6299 South Street

Halifax, Nova Scotia

Canada

B3H 4H6

+1 902 494 6513

researchservices@dal.ca

Sponsor type

University/education

Website

<http://www.dal.ca/research/>

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

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	04/06/2013		Yes	No