

PROphylaxis for ThromboEmbolism in Critical Care Trial (PROTECT)

Submission date 21/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 21/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/04/2019	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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00182143

Protocol serial number
MCT-78568; ACTRN12606000090516

Study information

Scientific Title

Low molecular weight heparin (LMWH) (dalteparin) versus unfractionated heparin (UFH) for deep vein thrombosis (DVT) prevention: a randomised, concealed, stratified, placebo-controlled, blinded, parallel assignment trial

Acronym

PROTECT

Study objectives

To evaluate the effect of low molecular weight heparin (LMWH) (dalteparin) versus unfractionated heparin (UFH) on the primary outcome of proximal leg deep vein thrombosis (DVT) diagnosed by compression ultrasound, and the secondary outcomes of pulmonary embolism (PE), bleeding, heparin-induced thrombocytopenia (HIT), and objectively confirmed venous thrombosis at any site.

Please note that this is a large-scale version of a previously registered pilot trial, 'PROphylaxis for ThromboEmbolism in Critical care Trial (PROTECT) pilot study' [ISRCTN54618366] (see <http://www.controlled-trials.com/ISRCTN54618366>). This large-scale version of the previous PROTECT Trial has been registered separately as changes to two of the exclusion criteria and one follow-up ultrasound of the protocol have been made between the pilot study and this large-scale trial.

As of 09/03/2009 this record was updated to include the addition of the United States of America as a country of recruitment, and an amended end date; the initial anticipated end date at the time of registration was 01/12/2011. All other changes can be found under the above date of update.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Canada: Research Ethics Board of McMaster University, Hamilton, Ontario on the 21st November 2005 and 21st November 2007 (ref: 05-2572)
2. Australia: Ethics Committee of Alfred Hospital on the 1st December 2003 (initially) (ref: 181/03) and on the 9th January 2006 (ref: 236/05)
3. Brazil: Comitê de Ética, Santa Casa de Misericórdian de Porto Alegre Hospital on the 27th July 2006 (ref: 1368/06) and the Comissão Nacional de Ética em Pesquisa (CONEP), Ministério da saúde on the 20th August 2007 (ref: 620/2007)
4. Saudi Arabia: Institutional Review Board of King Faisal Specialist Hospital and Research Centre on the 13th March 2006 (initially) (ref: RC(J)103E/27) and on the 24th October 2007 (ref: RC(J) 334M/28)

Added 09/03/2009:

5. USA: Rhode Island Hospital IRB gave approval in April 2008

Primary study design

Interventional

Study design

Interventional, randomised, double blind (subject, caregiver, investigator and outcomes assessor), placebo-controlled, parallel assignment, safety/efficacy study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Critical illness, deep vein thrombosis

Interventions

1. Drug: LMWH (dalteparin), 5,000 IU daily and placebo
2. Unfractionated heparin (UFH), 5,000 IU twice daily

The followup duration is to hospital discharge (which will vary for each patient).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dalteparin, unfractionated heparin

Primary outcome(s)

To evaluate the effect of LMWH (dalteparin) versus UFH on the primary outcome of proximal leg DVT diagnosed by compression ultrasound. Time frame: while in ICU to a maximum of 90 days.

Key secondary outcome(s)

To evaluate the effect of LMWH (dalteparin) versus UFH on the secondary outcomes of PE, bleeding, HIT, and objectively confirmed venous thrombosis at any site. Time frame: while in ICU to a maximum of 90 days.

Completion date

12/12/2010

Eligibility**Key inclusion criteria**

1. Admission to Intensive Care Unit (ICU)
2. Men or women greater than or equal to 18 years of age
3. Actual body weight greater than or equal to 45 kg
4. Admission to ICU expected to be greater than or equal to 72 hours in duration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Trauma, post-orthopedic surgery or post-neurosurgery patients
2. Uncontrolled hypertension (systolic greater than 180 mmHg or diastolic greater than 110 mmHg)
3. Major haemorrhage, haemorrhagic stroke, DVT or PE on admission or within last three months
4. Coagulopathy as defined by international normalised ratio (INR) greater than two times upper limit of normal [ULN], or partial thromboplastin time (PTT) greater than two times ULN
5. Thrombocytopenia defined as platelet count less than or equal to $75 \times 10^9/L$
6. Need for oral or intravenous or subcutaneous therapeutic anticoagulation
7. Receipt of greater than three days of UFH or LMWH in ICU
8. Contraindication to heparin (e.g., suspected HIT), blood products or pork products
9. Pregnant or lactating
10. Withdrawal of life support or limitation of life support
11. Current enrolment in this trial or a related trial
12. Lack of informed consent

Date of first enrolment

01/05/2006

Date of final enrolment

12/12/2010

Locations**Countries of recruitment**

Australia

Brazil

Canada

Saudi Arabia

United States of America

Study participating centre

St Joseph's Hospital

Hamilton, Ontario

Canada

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Sponsor information

Organisation

Hamilton Health Sciences (Canada)

ROR

<https://ror.org/02dqdxm48>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-78568)

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	01/06/2014	10/04/2019	Yes	No
Results article	results	01/12/2016	10/04/2019	Yes	No
Results article	results	01/12/2013	10/04/2019	Yes	No
Results article	results	07/04/2011	10/04/2019	Yes	No
Results article	results	01/09/2015	10/04/2019	Yes	No
Results article	results	01/10/2013	10/04/2019	Yes	No
Protocol article	protocol	01/04/2011	10/04/2019	Yes	No
Other publications	economic evaluation	20/12/2014	10/04/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes