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PROphylaxis for ThromboEmbolism in Critical Care Trial (PROTECT)

Submission date	Recruitment status	[_] Prospectively registered
21/05/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2019	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://clarityresearch.ca/protect/protect_trial/index.php

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00182143

Secondary identifying numbers
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 Misericordian de Porto Alegre Hospital on the 27th July 2006 (ref: 1368/06) and the Comissâo 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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/05/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3650

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 x 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
L8N 4A6

Sponsor information

Organisation
Hamilton Health Sciences (Canada)

Sponsor details
1200 Main Street West
Hamilton, Ontario
Canada
L8N 3Z5

Sponsor type
Research organisation

Website
http://www.hamiltonhealthsciences.ca/

ROR
https://ror.org/02dqdxm48

Funder(s)

Funder type
Research organisation

Funder Name

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?
Other publications	economic evaluation	20/12/2014	10/04/2019	Yes	No
Protocol article	protocol	01/04/2011	10/04/2019	Yes	No
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