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PROphylaxis of ThromboEmbolism in Critical care Trial (PROTECT) Trial: a pilot study

Submission date	Recruitment status	[_] Prospectively registered
01/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2009	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00182143

Secondary identifying numbers

MCT-57094

Study information

Scientific Title
A randomised controlled pilot study on low molecular weight heparin (LMWH) versus unfractionated heparin (UFH) in thromboembolism in critical care

Acronym
PROTECT

Study objectives
We hypothesised that we would achieve the four feasibility objectives of the PROTECT Pilot.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McMaster University Research Ethics Board approved on the 14th March 2002.

Study design
Randomised controlled trial

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
Medical-surgical Intensive Care Unit (ICU) patients

Interventions
LMWH (dalteparin 5000 IU once daily and placebo once daily) or UFH (5000 IU twice daily).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Heparins

Primary outcome measure
Scientific:
To establish the effect of LMWH versus UFH on DVT rates in medical-surgical ICU patients.

Feasibility:
1. The feasibility of timely enrolment and complete, blinded study drug administration
2. The bioaccumulation of LMWH in patients with acquired renal insufficiency and its association with bleeding
3. The feasibility of scheduled twice weekly lower limb ultrasounds
4. Recruitment rates for a future randomised trial

Secondary outcome measures
Scientific:
Among medical-surgical ICU patients, to establish the effect of LMWH versus UFH:
1. On PE (PE diagnosed by the PE diagnosis algorithm)
2. On bleeding events
3. On anti-Xa levels, and thus, the need for dose adjustment
4. On thrombocytopenia and heparin-induced thrombocytopenia

Overall study start date
01/02/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Admission to Intensive Care Unit (ICU)
2. Either sex, 18 years of age or over
3. Expected ICU admission more than or equal to 72 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
128

Key exclusion criteria

1. Diagnosis of trauma, post-orthopedic surgery, or neurosurgery at ICU admission
2. Severe hypertension (systolic blood pressure more than or equal to 180 mmHg for two hours or more) at ICU admission. Intracranial haemorrhage at ICU admission or within three months.
3. Known deep vein thrombosis (DVT), pulmonary embolism (PE) or major haemorrhage at ICU admission. Coagulopathy (defined as international normalised ratio [INR] values more than or equal to two times upper limit of normal).
4. Platelet count more than or equal to 50 x 10^9/l. Current therapeutic oral or intravenous anticoagulation for any reason. Current administration of activated protein. Estimated creatinine clearance less than or equal to 30 ml/min.
5. History of allergy to heparin or heparin-induced thrombocytopenia (HIT)
6. Receipt more than or equal to two doses of either low molecular weight heparin (LMWH) or unfractionated heparin (UFH) in ICU or Critical Care Unit (CCU)
7. Pregnancy
8. Limitation of life support or palliative care
9. No informed consent
10. Prior enrolment in this trial or currently in another related randomised trial

Date of first enrolment
01/02/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Australia

Canada

Singapore

United States of America

Study participating centre
McMaster University
Hamilton, Ontario
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Sponsor information

Organisation
McMaster University Medical Centre (Canada)

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05jyrng31

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-57094)

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	01/12/2005		Yes	No