# 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 [ ] Statistical analysis plan Registration date Overall study status 01/09/2005 Completed [X] Results Individual participant data **Last Edited** Condition category 03/03/2009 Surgery

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

### Type(s)

Scientific

#### Contact name

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# Additional identifiers

ClinicalTrials.gov (NCT) NCT00182143

Protocol serial number 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

### Study type(s)

Treatment

### 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(s)

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

### Key secondary outcome(s))

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

### 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

### Healthy volunteers allowed

No

### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

### 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  $50 \times 10^9$ /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

L8N 3Z5

United States of America

Study participating centre McMaster University Hamilton, Ontario Canada

# Sponsor information

### Organisation

McMaster University Medical Centre (Canada)

### **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**

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