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Clinically important venous thromboembolism following lower extremity fractures: epidemiology and prevention

Submission date	Recruitment status
24/02/2006	No longer recruiting
Registration date	**Overall study status**
24/02/2006	Completed
Last Edited	**Condition category**
31/01/2019	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rita Selby

Contact details
Sunnybrook and Women's College
Health Sciences Centre
Room D674a
2075 Bayview Avenue
Toronto
Canada
M4N 3M5
+1 416 480 6100 ext 2796
rita.selby@sw.ca

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00187408

Protocol serial number
DCT-49980

Study information

Scientific Title
A double-blind, randomized controlled trial of the prevention of clinically important venous thromboembolism after isolated lower leg fractures.

Acronym
D-KAF

Study objectives
To determine the incidence of clinically important venous thromboembolism (VTE) and the efficacy, safety and cost-effectiveness of anticoagulant prophylaxis with a low molecular weight heparin (LMWH) in patients with lower leg fractures requiring surgical repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board, Sunnybrook and Women's College Health Science Centre, Toronto, Ontario, Canada (4 December, 2001).

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Isolated below-knee fractures (tibia and/or fibula) requiring surgical repair

Interventions
Eligible consenting patients are randomized to receive either LMWH, dalteparin, 5000 anti-X-a units subcutaneously once daily, or placebo, within 72 hours of injury for 14 + 2 days. Patients are investigated for symptomatic VTE with objective diagnostic tests and pre-specified algorithms. All asymptomatic patients are screened with bilateral proximal duplex venous ultrasound at 14 + 2 days and followed up at 6 weeks and 3 months by telephone to assess for development of symptomatic VTE. CBC, INR, aPTT and creatinine are performed at baseline and CBC is repeated at the 14 + 2 day visit to check platelet count.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
LMW heparin, dalteparin

Primary outcome(s)
Clinically important venous thromboembolism at 3 months

Key secondary outcome(s))
1. Clinically important VTE during the prophylaxis phase (day 0-14 + 2)
2. Symptomatic VTE (either symptomatic deep vein thrombosis [DVT] or pulmonary embolism [PE] or fatal PE) during the post-prophylaxis phase (day 14 + 2 to 3 months + 1 week)
3. Bleeding
4. Cost-effectiveness

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Age >16 years, either sex
2. Unilateral or bilateral, closed or open, fractures of the lower extremity distal to the knee including:
a. Isolated fractures of the tibia including tibial plateau, shaft and plafond and medial malleolus
b. Isolated fractures of the fibula including fibular head, fibular diaphysis, distal fibula and lateral malleolus
c. Combined fractures of the tibia and fibula
3. Tibia and/or fibula fractures may be accompanied by fractures of the patella and/or foot as well as ligamentous injuries as long as either the tibia or the fibula is involved
4. Patients must be scheduled to undergo surgery (internal or external fixation) for repair of their fracture during the current admission

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients presenting greater than 72 hours after injury
2. Major injury involving other site(s)
3. Lower extremity vascular injury requiring surgical repair
4. Known systemic bleeding disorder or international normalized ratio (INR) >1.5, aPTT >40 sec, or platelets <50 x 10^9/l at baseline
5. Active, uncontrolled bleeding (as determined by the attending surgeon or delegate)
6. Intracranial or other major bleed in the previous 4 weeks
7. Ongoing need for anticoagulation for other reasons
8. Previous DVT or PE (objectively proven or treated with anticoagulants)

9. Known molecular hypercoagulable state
10. Active cancer
11. Inability to receive contrast dye because of pregnancy, contrast allergy, or renal failure (serum creatinine >300 µmol/l)
12. Hypersensitivity to heparin or LMWH (including history of HIT)
13. Inability to arrange out-of-hospital study medication administration
14. Anticipated inability to undergo endpoint duplex ultrasound or follow-up (day 14 + 2, 6 weeks, 3 months)
15. Inability or refusal to provide informed consent
16. Previous participation in this study
17. Estimated weight less than 40 kg

Date of first enrolment
01/08/2002

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Canada

Study participating centre
Sunnybrook and Women's College
Toronto
Canada
M4N 3M5

Sponsor information

Organisation
University of Toronto (Canada)

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: DCT-49980)

Funder Name
Pharmacia (Canada)

Funder Name
Pfizer Canada Inc. (Canada)

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	01/05/2015	31/01/2019	Yes	No