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A randomised clinical trial to compare the AV impulse foot pump with low molecular weight Heparin in the prevention of deep vein thrombosis after total knee replacement

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
22/02/2008

Condition category
Surgery

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R/41/1.97/Warw

Study information

Scientific Title

Study objectives
What is the relative effectiveness (against deep vein thrombosis [DVT]), safety and cost of Low Molecular Weight Heparin and the AV Impulse Foot Pump after total knee replacement surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Our study had the approval of the local Medical Research and Ethics Committee.

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
Total knee replacement

Interventions
Enoxaparin (40 mg) was administered, subcutaneously, 12 hours before surgery (in accordance with the UK licence) and every 24 hours thereafter until discharge from hospital. The slippers for the foot pump were applied in the recovery room and the controller was then engaged. The foot pump was then used whenever the patient was not weight-bearing until discharge from hospital. The patient lay in bed with the legs parallel to the floor. The controller activated the pump every 20 seconds at a pressure of 130 mmHg for a period of one second.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Enoxaparin

Primary outcome measure
Frequency of DVT as shown by the results of ipsilateral ascending venography between the sixth and eighth postoperative days.

Secondary outcome measures
1. Perioperative blood loss: a single drain was used routinely and blood loss was derived from a summation of intraoperative blood loss and postoperative drainage at 36 hours
2. Haemoglobin and haematocrit: measured before operation, on the second day after surgery and just before discharge
3. Blood loss index: transfusion requirements of the patients were noted. We recorded whether or not the patient had bruising or oozing from the site of the wound on the fourth and seventh postoperative days.
4. Swelling: assessed by measuring the circumference of the thigh and calf at 10 cm above and below the joint, respectively on the fourth and seventh postoperative days. The level was marked by an indelible pen to maintain consistency.
5. Knee flexion: measured active knee flexion with a goniometer on the fourth and seventh postoperative days. The soft-tissue side-effects were assessed in an open-label manner as it was apparent whether or not the patient was using a foot pump.

Overall study start date
01/08/1997

Completion date
01/02/1999

Eligibility

Key inclusion criteria
Patients scheduled for unilateral primary total knee replacement at the Avon Orthopaedic Centre.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
229

Key exclusion criteria

1. Refusal of consent
2. Long-term warfarin therapy for pre-existing cardiac or cerebral disease
3. A bleeding tendency
4. Painful joints or wounds in the feet which would preclude the use of the foot pump

Date of first enrolment
01/08/1997

Date of final enrolment
01/02/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton University Hospitals NHS Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (UK)

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	01/04/2002		Yes	No