

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	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/02/2008	Condition category Surgery	☐ 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

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (UK)

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	01/04/2002		Yes	No