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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

**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.

### Study design
Randomised controlled trial

### Primary study design
Interventional

### 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
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## 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 |