

# 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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/02/2008	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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

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**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?
<a href="#">Results article</a>	Results	01/04/2002		Yes	No