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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 hip 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**
Circulatory System

[_] 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
Without prophylaxis, 45% of patients develop a deep vein thrombosis (DVT) after total hip replacement (THR). Prophylaxis is mandatory to reduce this potentially fatal complication. Low molecular weight heparin (LMWH) is well-established as the most effective method available, reducing the rate to 19% but carrying a perceived risk of haemorrhagic complications. The AV Impulse Foot Pump is a promising new device. Early reports (three relatively small randomised studies) report a DVT rate of 7 to 13%, without haemorrhagic complications. LMWH has not been directly compared with the Foot Pump. A large randomised study is required to determine which of these two prophylactic measures is most effective against DVT, with least complications, best patient acceptability and most favourable cost-benefit ratio.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### 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
Cardiovascular diseases: Thromboembolic disease

### Interventions
1. Foot pump
2. Low molecular weight heparin

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
The prevalence of deep-vein thrombosis, as determined by venography on the sixth, seventh, or eighth postoperative day.

### Secondary outcome measures
1. Transfusion requirements
2. Intraoperative blood loss
3. Postoperative drainage
4. Blood-loss index
5. Appearance of the site of the wound according to a subjective visual-analogue scale
6. Swelling of the thigh.

### Overall study start date
01/01/1995

### Completion date
31/12/1997

## Eligibility

### Key inclusion criteria
300 consecutive primary Total Hip Replacement patients; randomised to have either Foot Pump or LMWH until discharge.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
290

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/01/1995

### Date of final enrolment
31/12/1997

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Southampton University Hospitals NHS Trust**
Southampton
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# Sponsor information

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

### Sponsor details
The Department of Health
Richmond House
79 Whitehall
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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 | 01/08/1998 | | Yes | No |