# 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	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/01/2004		Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/02/2008	Circulatory System			

### Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr David Warwick

### Contact details

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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
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 79 Whitehall 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	01/08/1998		Yes	No