

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	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/02/2008	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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	01/08/1998		Yes	No