ISRCTN17418323 https://doi.org/10.1186/ISRCTN17418323

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

Contact name
Mr David Warwick

Contact details
Southampton University Hospitals NHS Trust
Department of Orthopaedic Surgery
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)23 8079 6245
davidwarwick@handsurgery.co.uk

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

Primary study design
Interventional

Study design
Randomised controlled trial

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