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Patency of luminal heparinised polytetrafluoroethylene (PTFE) grafts compared with unheparinised PTFE grafts

Submission date 03/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/10/2005	**Overall study status** Completed	
Last Edited 20/08/2009	**Condition category** Circulatory System	

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

N/A

Study information

Scientific Title

Study objectives
Endoluminal heparinised polytetrafluoroethylene (PTFE) grafts reduces early occlusion.

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
Lower limb ischaemia

Interventions
Use of endoluminal heparinised PTFE graft instead of unheparinised PTFE grafts.

Please note that recruitment for this trial completed on 31/12/2008 and the trial is in follow-up as of 20/08/2009. Publication expected in Autumn 2010.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patency

Secondary outcome measures
1. Secondary interventions
2. Cost effectiveness
3. Amputations

Overall study start date
01/07/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients with chronic lower limb ischeamia, who require a femoropopliteal or femorofemoral bypass with the use of an artificial graft

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
484

Key exclusion criteria
Acute lower limb ischaemia, expected poor surveillance postoperatively, heparin allergy

Date of first enrolment
01/07/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Denmark

Study participating centre
Vascular Research Unit
Viborg
Denmark
8800

Sponsor information

Organisation
W. L. Gore and Associates (Sweden)

Sponsor details
Box 268
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Sweden
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Sponsor type
Industry

Website
http://www.gore.com

ROR
https://ror.org/0428qnk54

Funder(s)

Funder type
Industry

Funder Name
Price difference of the two types of grafts is covered by W. L. Gore and Associates (Sweden)

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