

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

Submission date 03/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/08/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jes Lindholt

Contact details
Vascular Research Unit
Viborg Hospital
Postbox 130
Viborg
Denmark
8800
+45 89272447
jes.s.lindholt@sygehusviborg.dk

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 ischaemia, 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
Mölndal
Sweden
SE-431 23
+46 45892650
lcederbye@wlgore.com

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