ISRCTN17706253 https://doi.org/10.1186/ISRCTN17706253

A double blind randomised controlled trial comparing porcine dermal collagen patch saphenoplasty with conventional saphenofemoral ligation to prevent recurrent saphenofemoral incompetence

Submission date 28/09/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 28/09/2007	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 05/09/2008	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

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
N0672184853

Study information

Scientific Title

Study objectives
To compare the use of porcine dermal collagen patch saphenoplasty with standard saphenofemoral flush ligation in primary and recurrent varicose vein surgery. Post-operative subjective and objective measures of the presence and severity of varicosity recurrence shall be compared.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind (patient and assessor blind) randomised controlled Study

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: Varicose veins

Interventions
Randomisation and Blinding:
Randomisation will be computer generated using the Statistical Package for Social Sciences (SPSS) and shall occur only once informed consent has been obtained and following induction of general anaesthesia. Each treatment, either porcine dermal collagen patch or saphenofemoral junction ligation alone will be documented on paper and placed in numbered envelopes and sealed. The envelopes will then be opened in numerical order. The surgeon will not know which mesh is to be used until the time the envelope is opened. The patient and post-operative

assessor will not know which mesh has been used in their operation.
A master list of the randomisation will be kept in the Research and Development Department and be used solely for code breaking purposes should any adverse events occur. Adverse events will be reported by study documentation and to the Trust Risk Management department in line with Trust procedure.

Surgery:
All surgery shall be performed under general anaesthesia. Patients shall receive deep vein thrombosis (DVT) prophylaxis where clinically appropriate and according to local protocols. Surgery shall be performed by the Principle and Co-Investigators using established standard techniques of saphenofemoral junction ligation and varicose vein surgery. Briefly, following dissection to demarcate the saphenofemoral junction all tributaries shall be ligated. Disconnection of the saphenofemoral junction shall then be followed by flush suture ligation using a polygalactin suture with stripping of the saphenous vein to below the knee. In the presence of bifid long saphenous veins each shall be disconnected and suture ligated separately. If randomized to PermacolTM group a small patch of porcine dermal collagen shall be sutured over the obliterated saphenofemoral junction prior to closure of the fascial layers. If randomized to the standard technique alone this step shall be omitted. Standardized wound closure and dressing shall be performed. Discharge shall be with standard simple analgesia after adequate voiding of urine and ambulation. It is anticipated that this shall be the same day for most patients. Patients shall receive instructions to remove their dressings on the third post-operative day and thereafter to wear a Class II compression stocking for 6 weeks.

Assessments:
At 1 and 5 years follow up, a Research Nurse assessor, blinded to the technique used, shall administer pain visual analogue scales and objective, validated measures of QoL; namely the Short Form 36TM (SF36TM) and EUROQOLTM questionnaires. Patients shall be clinically examined for evidence of recurrent varicose veins and an objective measure of severity recorded using the venous disability score (VDS), venous clinical severity score (VCSS) and venous segmental disease score (VSDS).
Patients shall undergo a hand held Doppler ultrasound examination of the saphenofemoral junction to document the presence of radiologically apparent recurrence. This shall be defined as the presence of a new vein with diameter at least 4 mm and with pathologic reflux in direct connection with incompetent varicose veins at thigh level.

Added 05 September 2008: recruitment never started on this site.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
porcine dermal collagen patch

Primary outcome measure
The study shall be designed to demonstrate a 50% reduction in the clinical presence of recurrence at 5 years. Therefore, the null hypothesis is that no statistically significant difference exists in the clinically assessed recurrence rates at 5 years between PermacolTM and standard surgical groups.

Secondary outcome measures
1. Annual clinical recurrence rates
2. Radiographically demonstrable recurrence rates at 1 year and 5 years
3. Visual analogue pain scores
4. SF36 and EUROQOL questionnaire scores
5. Local complication rate: fistula, haematoma, groin wound infection
6. Serious adverse event rates

Overall study start date
10/07/2006

Completion date
09/07/2011

Reason abandoned (if study stopped)
Never started.

Eligibility

Key inclusion criteria
All patients with primary or recurrent, uni or bilateral varicose veins with clinical evidence of saphenofemoral incompetence and who fulfill the following criteria will be considered eligible for the trial:
1. Clinically fit for general anaesthesia
2. Have the need for saphenofemoral junction ligation during varicose vein surgery
3. Should have the legal age and ability to provide informed consent
4. Have no known allergies to the products being tested
5. Agree to their GP being informed of their participation

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
To achieve adequate compliance with the protocol and follow up it is anticipated that 80 patients in total will be recruited. 40 patients will be randomly allocated into each arm of the study.

Key exclusion criteria
1. Patients not able or unwilling to provide informed consent
2. Undergoing formal anti-coagulation for previous thromboembolic phenomena
3. Known allergies to the products being investigated
4. Do not agree to their GP being informed of their participation

Date of first enrolment

10/07/2006

Date of final enrolment
09/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Northern Lincolnshire and Goole Hospitals NHS Trust (UK), R&D Department supports admin cost

Funder Name
Permacol is provided free of charge by Tissue Science Laboratories (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