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

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/10/2010	**Overall study status** Completed	
Last Edited 18/04/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
6006

Study information

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

Study objectives
The study aims 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 presence and severity of varicosity recurrence shall be compared. This shall be the first study to establish the efficacy of Permacol™ in this setting, and shall use the following endpoints to test the given null hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 06/Q1105/27

Study design
Multicentre non-randomised observational case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Surgery

Interventions
1. Imaging investigations (non-radiation): Patients need to undergo a handheld Doppler ultrasound examination of the saphenofemoral junction to document the presence of radiologically apparent recurrence.
2. Other examinations: Patients shall be clinically examined for evidence of recurrent varicose veins
3. Questionnaire: A research nurse assessor, blinded to the technique used, shall administer a questionnaire at 1 and 5 years follow-up

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
50% reduction in the clinical presence of recurrence at 5 years.

Key secondary outcome(s))

1. Annual clinical recurrence rates
2. Local complication rate - fistula, haematoma, groin wound infection
3. Radiographically demonstrable recurrence rates at 1 year and 5 years
4. Serious adverse event rates
5. 36-item short form health survey (SF-36) and EUROQOL questionnaire scores
6. Visual analogue pain scores

Completion date
09/07/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
10/07/2006

Date of final enrolment
09/07/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Diana, Princess of Wales Hospital
Grimsby
United Kingdom
DN33 2BA

Sponsor information

Organisation
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/01ep18d71

Funder(s)

Funder type
Industry

Funder Name
Tissue Science Laboratories PLC (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration