

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
Registration date 21/10/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/04/2017	Condition category Surgery	☐ 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

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

Primary study design

Observational

Study design

Multicentre non-randomised observational case-control study

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