

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

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<b>Registration date</b> 21/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Surgery	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

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

## Secondary study design

Case-control study

## Study setting(s)

GP practice

## Study type(s)

Diagnostic

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## 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 measure**

50% reduction in the clinical presence of recurrence at 5 years.

**Secondary outcome measures**

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

**Overall study start date**

10/07/2006

**Completion date**

09/07/2011

## **Eligibility**

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Planned sample size: 100

**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**

England

United Kingdom

**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)

**Sponsor details**

Research and Development Department

Scunthorpe General Hospital

Cliff Gardens

Scunthorpe

England

United Kingdom

DN15 7BH

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nlg.nhs.uk>

**ROR**

<https://ror.org/01ep18d71>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Tissue Science Laboratories PLC (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