

# Antibiotic prophylaxis in varicose vein surgery

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/01/2010	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Ian Chetter

**Contact details**  
Dept of Vascular Surgery  
Hull Royal Infirmary  
Hull  
United Kingdom  
HU3 2JZ

## Additional identifiers

**Protocol serial number**  
N0084125086

## Study information

**Scientific Title**  
A double blinded randomised controlled trial of antibiotic prophylaxis in varicose vein surgery

**Study objectives**  
To compare antibiotic prophylaxis with no antibiotic, with primary endpoint being the rate of wound infection.

Please note that as of 13/02/2009 this record was extensively updated. All amendments can be found in the relevant field under the above update date.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Added 13/02/2009: Hull and East Riding Local Research Ethics Committee gave approval on the 23rd September 2002 (ref: LREC/08/02/135)

### **Study design**

Double blinded randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Surgery: Varicose vein

### **Interventions**

1. Antibiotics (Augmentin 1.2 g)
2. No antibiotics

The treatment was a one-off treatment (varicose vein surgery), which lasted a range of 44 - 65 minutes. Patients were seen once at 14 days post-operation.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Applicable

### **Primary outcome(s)**

Added 13/02/2009:

The degree of wound complications, determined by an adapted version of the ASEPSIS wound scoring system.

### **Key secondary outcome(s)**

Added 13/02/2009:

1. Visit to the General Practitioner for a wound-related problem
2. The requirement of antibiotics in the post-operative period for a perceived wound infection

### **Completion date**

01/06/2006

## **Eligibility**

**Key inclusion criteria**

Added 13/02/2009:

1. Aged 18 years or older, either sex
2. Undergoing groin surgery for varicose veins. All patients with varicosities of the greater saphenous vein (GSV) listed for saphenofemoral ligation, stripping of the GSV and phlebectomies were eligible to enter the trial.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Added 13/02/2009:

1. Patients whose surgery did not include a groin incision
2. Patients below the age of 18 years
3. Pregnancy or lactation
4. Penicillin allergy
5. Receiving antibiotics for other indications

**Date of first enrolment**

09/04/2003

**Date of final enrolment**

01/06/2006

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Dept of Vascular Surgery**

Hull

United Kingdom

HU3 2JZ

# Sponsor information

## Organisation

Department of Health

## Funder(s)

### Funder type

Government

### Funder Name

The North and South Bank Research and Development Consortium (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2010		Yes	No