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Antibiotic prophylaxis in varicose vein surgery

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 05/01/2010	**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
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)

Primary study design
Interventional

Study design
Double blinded randomised controlled trial

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?
Results article	results	01/01/2010		Yes	No