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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

Contact name
Mr Ian Chetter

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure

Added 13/02/2009:
The degree of wound complications, determined by an adapted version of the ASEPSIS wound scoring system.

Secondary outcome measures
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

Overall study start date
09/04/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
572

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
England

United Kingdom

Study participating centre
Dept of Vascular Surgery
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No