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Reduction of leg wound complications following coronary artery bypass grafting

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2009	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
N0185115619

Study information

Scientific Title

Study objectives

To determine the best method for leg wound closure. The choice of wound closure technique may have important implications for post operative healing in these high risk cases, and also have an impact in other patients at lower risk for post operative morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Coronary artery bypass grafting (CABG)

Interventions
A prospective randomised controlled trial performed at the Southwest Cardiothoracic Centre. Recruitment of patients will be over a period of 6 months. Patients will be followed from the day of operation to the time of discharge from the hospital and for a period of 6 weeks thereafter. Patients will be randomised to two equal sized groups.

Patients will be randomly assigned to one of two groups:
1. Single layer wound closure over Redivac drains
2. 2-layer closure +/- Redivac drains as indicated clinically.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Post operative healing

Key secondary outcome(s)
Not provided at time of registration

Completion date
25/04/2003

Eligibility

Key inclusion criteria

80 Patients undergoing CABG surgery will be enrolled into the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
25/10/2002

Date of final enrolment
25/04/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cardiothoracic Theatres
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Plymouth Hospitals NHS Trust (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	01/12/2005		Yes	No