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Internal mammary artery harvest with papaverine vs saline infiltration

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2015	Surgery	[ ] 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
N0436176306

Study information

Scientific Title
Internal mammary artery harvest with papaverine vs saline infiltration

Study objectives
To see whether infiltrating papaverine into endothoracic fascia while harvesting compared to saline as reported in literature makes any difference in terms of spasm, size and flow difference in the mammary conduit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East Ethics Committee, ref 05/Q1206/185

Study design
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: Coronary artery bypass graft (CABG)

Interventions
Internal thoracic artery (IMA) harvest with papaverine vs normal saline infiltration into endothoracic fascia

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Papaverine

Primary outcome measure
To see the difference in quality of mammary artery conduit with two different methods of harvesting (quality of the mammary artery that includes the spasm, flow and appearances).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2006

Completion date
01/07/2008

Eligibility

Key inclusion criteria
All patients having coronary artery bypass surgery where artery behind the breast bone is used will be invited to take part.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50 with 25 in each group

Key exclusion criteria
1. Patients not willing to participate
2. Internal Mammary Artery (IMA) not used

Date of first enrolment
01/02/2006

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
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SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK), NHS R&D Support Funding

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