

Internal mammary artery harvest with papaverine vs saline infiltration

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| Submission date 29/09/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/09/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 29/01/2015 | Condition category Surgery | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
United Kingdom
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