

Prospective randomised study of minimal invasive vs open surgery for treatment of benign breast lesions.

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/07/2013	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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0084125093

Study information

Scientific Title

Study objectives

To evaluate comparative cosmetic outcome between open and minimal invasive surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

Health condition(s) or problem(s) studied

Surgery: Breast lesions

Interventions

Randomised controlled trial (RCT) comparing:

1. Minimally invasive surgery
2. Open surgery

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Cosmetic outcomes

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/04/2003

Completion date

01/12/2005

Eligibility

Key inclusion criteria

40 patients with benign breast lesions will be recruited

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

40

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

10/04/2003

Date of final enrolment

01/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Surgical Unit

Cottingham

United Kingdom

HU16 5JQ

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

Not defined

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