

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	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 30/07/2013	Condition category Surgery	☐ Individual participant data
		☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Cosmetic outcomes

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2005

Eligibility**Key inclusion criteria**

40 patients with benign breast lesions will be recruited

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Academic Surgical Unit

Cottingham

United Kingdom

HU16 5JQ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Not defined

Funder Name

The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration