

A randomised three-way comparison of mastectomy performed using Lotus Ultrasonic Cutting and Coagulation Device, Ethicon Harmonic Scalpel or monopolar diathermy

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/05/2017	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

N0185168728

Study information

Scientific Title

A randomised three-way comparison of mastectomy performed using Lotus Ultrasonic Cutting and Coagulation Device, Ethicon Harmonic Scalpel or monopolar diathermy

Study objectives

Are the Lotus UCCD and Ethicon Harmonic Scalpel and monopolar diathermy equivalent to each other for tissue dissection during a mastectomy?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cornwall and Plymouth Research Ethics Committee (UK), August 2005, ref: REC no: 05/Q2103/71

Study design

Three-way randomised comparison 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: Mastectomy

Interventions

Three-way randomised comparison trial: Lotus Ultrasonic Cutting and Coagulation Device, Ethicon Harmonic Scalpel or monopolar diathermy.

Intervention Type

Device

Phase

Not Applicable

Primary outcome measure

Post-operative drainage.

1. Blood loss
2. Duration of operation
3. Extent of collateral tissue damage
4. Opinion of operating surgeon
5. Post-operative pain
6. Duration of post-operative hospital stay
7. Seroma and infection rates

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/08/2005

Completion date

31/10/2007

Eligibility

Key inclusion criteria

Patients for routine, elective unilateral or bilateral mastectomy with or without simultaneous axillary node dissection.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

90 patients will be recruited, 30 will be randomised to each group.

Key exclusion criteria

1. Pregnant or lactating women
2. Patients under 18 years
3. Patients above 75 years
4. History of coagulation abnormality
5. Inability to understand the nature of this study

Date of first enrolment

31/08/2005

Date of final enrolment

31/10/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

c/o Mr K Hosie Secretary

Plymouth

United Kingdom

PL6 8DH

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

Plymouth Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding (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