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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

Registration date
29/09/2006

Overall study status
Completed

Last Edited
22/05/2017

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

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 with out 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
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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
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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