

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

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

Mrs Emma Noble

### Contact details

c/o Mr K Hosie Secretary

Level 07

DerriFord Hospital

Plymouth

United Kingdom

PL6 8DH

+44 (0)7968919208

em2\_whitehead@hotmail.com

## Additional identifiers

### Protocol serial number

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

**Primary study design**

Interventional

**Study design**

Three-way randomised comparison trial

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### 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

United Kingdom

England

### 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

## Funder(s)

### Funder type

Government

### Funder Name

Plymouth Hospitals NHS Trust (UK)

### Funder Name

NHS R&D Support Funding (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration