

# Randomised clinical trial of longitudinal versus torsional mode ultrasound in laparoscopic cholecystectomy

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/07/2009	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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**

## Study information

### Scientific Title

### Study objectives

To compare torsional mode ultrasound with longitudinal mode ultrasound with regard to safety and efficiency in haemostatic cutting in laparoscopic surgery.

Please note that this record has been updated as of 29/04/2008. All updates can be found in the relevant field, under the above date. Please also note that the anticipated end date of this trial has been updated to 14/11/2007. The previous anticipated end date was 01/09/2004.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Added as of 29/04/2008:

Ethics approval received from the Leeds (West) Research Ethics Committee (ref: 03/009 and 04/Q1205/143).

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied

Surgery: Laparoscopy

### Interventions

Randomised controlled trial. Random allocation to:

A. Longitudinal Mode Ultrasound

B. Torsional Mode Ultrasound

### Intervention Type

Procedure/Surgery

**Phase**

Not Specified

**Primary outcome measure**

Current primary outcomes as of 29/04/2008:

Operative blood loss, calculated within 24 hours post surgery.

Previous primary outcomes:

Operating time, blood loss, post operative complications.

**Secondary outcome measures**

Added as of 29/04/2008:

1. Gallbladder dissection time, measured during laparoscopic cholecystectomy
2. Gallbladder perforation rate, measured during laparoscopic cholecystectomy
3. Need for monopolar electrocoagulation, measured during laparoscopic cholecystectomy
4. Complications, recorded post-operatively

**Overall study start date**

01/01/2003

**Completion date**

14/11/2007

**Eligibility****Key inclusion criteria**

Patients undergoing laparoscopic cholecystectomy.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

160 (added 29/04/2008)

**Key exclusion criteria**

Added as of 29/04/2008:

1. Oral anticoagulant treatment
2. Known coagulation disorder
3. American Society of Anaesthesiologists (ASA) grade 3 or more
4. Aged less than 16 years
5. Pregnancy
6. Mental illness
7. The need to explore the common bile duct at the time of surgery

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

14/11/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

D Floor, Clarendon Wing

Leeds

United Kingdom

LS1 3EX

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Leeds Teaching Hospitals NHS Trust (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2009		Yes	No