

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/07/2009	Condition category Surgery	☐ 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

Protocol serial number
N0436121394

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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

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

Completion date

14/11/2007

Eligibility

Key inclusion criteria

Patients undergoing laparoscopic cholecystectomy.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

D Floor, Clarendon Wing
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

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?
Results article	results	01/07/2009		Yes	No