ISRCTN87527062 https://doi.org/10.1186/ISRCTN87527062

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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2009	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr SS Ching

Contact details
D Floor, Clarendon Wing
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 3922247
ching_ss@hotmail.com

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).

Study design
Randomised controlled trial

Primary study design
Interventional

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