

Clinical relevance study for a novel ultrasonic dissection cutter versus conventional mobilisation/dissection in open stomach and colon procedures

Submission date 15/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/11/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2017	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

N/A

Study information

Scientific Title

Clinical relevance study for a novel ultrasonic dissection cutter versus conventional mobilisation /dissection in open stomach and colon procedures - a randomised controlled study

Study objectives

In technically demanding visceral operations such as gastrectomy and colon resection, precision and a mobilisation technique with little or no bleeding are of special significance. The hypothesis is that WAVE ultrasonic technology is particularly suitable for reducing the total operating time because it generates very little heat in the surrounding tissue, enabling safe, atraumatic surgical dissection in combination with simultaneous haemostasis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the Ethics Review Board (ERB) of Klinikum rechts der Isar on the 18th October 2007

Study design

Prospective, two-arm, randomised, controlled clinical study

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

Gastric carcinoma, colon carcinoma

Interventions

Treatment Arm A (WAVE ultrasound dissector):

The operation is performed as described in the surgical report. The WAVE ultrasound dissector is exclusively used for dissection and coagulation.

Treatment Arm B (conventional mobilisation/dissection):

The operation is performed as described in the surgical report. Dissection and coagulation are performed exclusively with instruments using mono- and bi-polar current or ligatures/stitches.

The follow up will take place during the whole in-hospital stay of the patient.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Reduction of operation time for total gastrectomy/colon resection with WAVE ultrasound dissector.

Secondary outcome measures

1. Reduction of intra-operative blood loss
2. Reduction of the quantity of drainage secretion and dwell time of the drain
3. Comparison of oncological (surgical margins) and functional outcomes between the different methods

Overall study start date

15/12/2007

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Gastric carcinoma, colon carcinoma
2. Patient's written declaration of informed consent after being given written and oral information
3. General status: operable according to American Society of Anaesthesiologists (ASA) categorisation of the risks of anaesthetic
4. Age over 18, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200 (100 in each arm)

Key exclusion criteria

1. Enrolment in other clinical trials that might interfere with the present study
2. Refusal of consent to the storage and communication of anonymised medical history data, previous psychiatric illness or other circumstances that might compromise the patient's co-operation

Exclusion of patients after enrolment in the trial:

1. Inoperability during the procedure; change of planned procedure
2. Withdrawal of consent

Date of first enrolment

15/12/2007

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Austria

Germany

Hungary

Italy

Study participating centre

Chirurgische Klinik und Poliklinik

Munich

Germany

81675

Sponsor information

Organisation

Ethicon Endo-Surgery (Europe) GmbH

Sponsor details

Hummelsbütteler Steindamm 71
Norderstedt
Germany
22851

Sponsor type

Industry

Website

<http://www.ethiconendo.com/>

ROR

<https://ror.org/023edjq13>

Funder(s)

Funder type

Industry

Funder Name

Ethicon Endo-Surgery (Europe) GmbH

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?
Results article	results	01/02/2011		Yes	No