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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/11/2008	**Overall study status** Completed	
Last Edited 13/09/2017	**Condition category** Cancer	

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. Wthdrawal 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