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Cost and efficacy of dissection devices in extended and parenchyma preserving liver resection: a prospective randomised trial

Submission date 01/07/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/08/2008	**Overall study status** Completed	
Last Edited 30/06/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Martin K Schilling

Contact details
Department of General-, Visceral- , Vascular- and Paediatric Surgery
University of Saarland
Homburg/Saar
Germany
66421

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
LDD (Liver Dissection Devices)

Study objectives
Evaluate the surgical safety and the costs of different commercially available liver dissection devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local Ethical Committee of the University of the Saarland in March 2005 (ref: 47/05)

Study design
Single-centre, randomised, single-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Primary or secondary hepatic malignacy

Interventions
Liver resection with three different liver resection (dissection) devices:
1. Selector® (Erbe, Tübingen, Germany)
2. Helix HydroJet® (Erbe, Tübingen, Germany)
3. Dissecting Sealer 3.0® (TissueLink Medical, Dover, NH, USA)

Total duration of follow-up in all treatment arms was until discharge from hospital, no further follow up was performed.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
1. Blood loss
2. Intraoperative and postoperative blood transfusions
3. Dissection time
4. Resection area
5. Dissection speed
6. Blood loss per dissected area
7. Post-operative International Normalised Ratio (INR)
8. Post-operative partial thromboplastin time (PTT)
9. Post-operative bilirubin levels
10. Morbidity (bleeding, bile fistula, cholangitis, liver abscess, pleura effusion, pneumonia, cardiac complications)
11. Intensive Care Unit (ICU) stay
12. Hospital stay

Primary and secondary outcomes were measured during the hospital stay.

Secondary outcome measures
1. Mounting time
2. Costs of devices (system costs)
3. Maintenance costs
4. Costs of additional haemostyptic items
5. Costs of staplers and magazines

Primary and secondary outcomes were measured during the hospital stay.

Overall study start date
01/09/2003

Completion date
30/06/2005

Eligibility

Key inclusion criteria
All patients undergoing liver resection for primary or secondary hepatic malignancy of any age and gender.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
96

Key exclusion criteria
1. Cirrhosis or cholestasis (serum bilirubin greater than 25 mg/dl)
2. Prior chemotherapy (within 6 months) and multiple liver tumours

Date of first enrolment
01/09/2003

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Germany

Study participating centre
Department of General-, Visceral- , Vascular- and Paediatric Surgery
Homburg/Saar
Germany
66421

Sponsor information

Organisation
University of Saarland (Germany)

Sponsor details
Department of General-, Visceral- , Vascular- and Paediatric Surgery
Kirrberger Strasse
Gebaeude 57
Homburg/Saar
Germany
66421

Sponsor type
University/education

Website
http://www.uni-saarland.de/en/

ROR
https://ror.org/01jdpyv68

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Germany)

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	01/06/2009		Yes	No