

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

<b>Submission date</b> 01/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/06/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Protocol serial number

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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Primary or secondary hepatic malignancy

### **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(s)**

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.

**Key secondary outcome(s))**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**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)

**ROR**  
<https://ror.org/01jdpv68>

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded (Germany)

## 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?
<a href="#">Results article</a>	results	01/06/2009		Yes	No