

Influence of two different resection techniques of liver metastases from colorectal cancer on haematogenous tumour cell dissemination

Submission date 08/12/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/11/2020	Condition category Cancer	<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

Protocol serial number
KSC 05/2003

Study information

Scientific Title

Influence of two different resection techniques of liver metastases from colorectal cancer on haematogenous tumour cell dissemination: a prospective randomised multicentre trial

Acronym

Anterior Approach Study

Study objectives

We hypothesise that intraoperative haematogenous tumour cell dissemination could be reduced or prevented by using the anterior approach technique in resection of colorectal liver metastases.

Please note that as of 11/02/2009 this record was updated to include an amended end date. The initial end date at the time of registration was:

Initial anticipated end date: 28/02/2009

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 11/02/2009: Ethics Committee of University of Heidelberg Medical School gave approval in October 2002.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Liver cancer

Interventions

Patients with liver metastases from colorectal cancer scheduled for a potentially curative normal or extended right hemihepactomy.

The study will be performed as a prospective randomised multicentre trial. Patients will be randomised intraoperatively in each institution: one group will undergo conventional liver resection and the other group will be operated with the anterior approach technique. On day 0 the patient will undergo exploration. In case of suspected extrahepatic spread (including grossly involved lymph nodes) frozen sections of the suspicious areas will be performed. All these procedures are considered routine and are carried out for any patient undergoing resection of liver tumours. Patients with positive extrahepatic spread (including positive lymph nodes) routinely do not undergo liver resection, these patients will therefore be excluded from the study. After extrahepatic tumour spread is excluded, the surgeon will again evaluate whether resection of the tumour can be performed by either technique. Once this

criteria is met, the patient will be randomised to one of the two groups: one group will undergo conventional liver resection and the other group will undergo resection using the anterior approach technique.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To compare the anterior approach to the conventional technique of hepatic resection for colorectal metastases with respect to the incidence of intraoperative haematogenous tumour cell dissemination. We hypothesise that intraoperative haematogenous tumour cell dissemination could be reduced or prevented by using the anterior approach technique in resection of colorectal liver metastases.

Key secondary outcome(s)

1. Survival of the patients (overall and disease-free survival)
2. Blood loss
3. Duration time of resection
4. Transfusion requirements
5. Complication rates

Assessed between the two different liver resection techniques. Furthermore the prognostic relevance of tumor cell detection in blood and bone marrow and the comparison of tumor cell detection by different detection methods will be analysed.

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Hospitalised patients of the Department of Surgery, University of Heidelberg or of the Hepatobiliary Division, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, aged greater than 18 years (no upper age limit)
2. Are considered for a potentially curative (R0) right hepatectomy (removal of segments 5,6,7,8), extended right hepatectomy (removal of segments 5,6,7,8, part of segment 4) or right trisegmentectomy (removal of segments 4,5,6,7,8) for colorectal liver metastases

There will be 150 patients (75 each group) accrued in this study (excluding patients who underwent R1 resection and/or with an intraoperative blood loss of greater than or equal to 2000 cc).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

80

Key exclusion criteria

Patients with positive extrahepatic spread (including positive lymph nodes) routinely do not undergo liver resection, these patients will therefore be excluded from the study.

Date of first enrolment

01/02/2003

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Germany

United States of America

Study participating centre

University of Heidelberg Medical School

Heidelberg

Germany

69120

Sponsor information**Organisation**

University of Heidelberg Medical School (Germany)

ROR

<https://ror.org/038t36y30>

Funder(s)

Funder type

University/education

Funder Name

University of Heidelberg (Germany) - Medical School

Funder Name

Jung Stiftung (Germany)

Alternative Name(s)

Jung Foundation for Science and Research, Jung-Stiftung

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

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?
Results article	results	01/01/2021	05/11/2020	Yes	No
Protocol article	Protocol	05/03/2008		Yes	No