ISRCTN45066244 https://doi.org/10.1186/ISRCTN45066244

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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/01/2005	**Overall study status** Completed	
Last Edited 05/11/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Markus W Büchler

Contact details
University of Heidelberg Medical School
Im Neuenheimer Feld 110
Heidelberg
Germany
69120
+49 6221 56 6200
markus.buechler@med.uni-heidelberg.de

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