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Outcomes of two-stage liver resection in the treatment of a rare type of primary liver cancer

Submission date
23/04/2022

Recruitment status
No longer recruiting

Registration date
16/06/2022

Overall study status
Completed

Last Edited
04/07/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Different approaches have been introduced for the treatment of patients with liver cancer. However, in some cases, surgical treatment is considered the best and only option to eliminate the disease and guarantee the patients a better therapeutic outcome. Cholangiocarcinoma is a liver cancer originating from biliary structures which can only be treated efficiently by liver surgery. Liver surgery is a major surgery with a wide range of risks, which might result in different complications and even death. Particularly in patients with cholangiocarcinoma, a large volume of the liver is removed during surgery to prevent the recurrence of the disease. This can lead to liver dysfunction and even more dangerous complications. Associating liver partition and portal vein ligation for staged hepatectomy (ALPPS) is a new technique for liver surgery which involves two stages of surgery and is believed to prevent hazardous complications after high-volume liver resection due to its stepwise process that provides the liver enough time for recovery. However, the outcomes of ALPPS in the treatment of patients with cholangiocarcinoma are not well-understood. This study evaluates the impact of ALPPS in the treatment of patients with cholangiocarcinoma.

Who can participate?
Patients with cholangiocarcinoma who underwent ALPPS between 2011 and 2021 at Heidelberg University Hospital

What does the study involve?
The outcomes of patients who have undergone the ALPPS procedure will be evaluated to assess the complications after surgery.

What are the possible benefits and risks of participating?
The results of the study will show the effectiveness of ALPPS in these patients.

Where is the study run from?
Heidelberg University Hospital (Germany)

When is the study starting and how long is it expected to run for?
January 2011 to January 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ali Ramouz
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Contact information

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Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Outcomes of modified associating liver partition and portal vein ligation for staged hepatectomy in cholangiocarcinoma

Acronym
HD-ALPPS

Study objectives
Modified associating liver partition and portal vein ligation for staged hepatectomy (ALPPS) provide better outcomes compared to conventional ALPPS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2018, Independent Ethics Committee of the University of Heidelberg (Alte Glockengießerei 11/1, 69115 Heidelberg, Germany; +49 (0)6221 562646-0; ethikkommission-I@med.uni-heidelberg.de), ref: S-754/2018

Study design
Interventional non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cholangiocarcinoma

Interventions
In 2016, the researchers started using the ALPPS risk score to preoperatively assess patients for the ALPPS procedure. Patients with cholangiocarcinoma relevant hyperbilirubinemia were candidates to undergo preoperative biliary drainage, to resolve the bile stasis and decrease the serum levels of bilirubin. The researchers also modified the standard ALPPS procedure by minimizing the first stage of the surgical procedure. The specific modification during the first stage involved delaying biliary reconstruction and externalization of biliary flow. The externalization of biliary flow was carried out to reduce the risk of bacteremia and decompressing the proximal bile duct. Thus, a pediatric feeding tube was inserted into the proximal bile duct. During the interphase stage, antibiotics were administered to all patients. Biliary reconstructions were performed during the second stage.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Postoperative morbidities classified as grade I to V based on the Clavien–Dindo classification during the hospital stay

Key secondary outcome(s))
1. Post-hepatectomy liver failure (PHLF) evaluated using the definition provided by the international study group of liver surgery (ISGLS), and classified respectively according to severity grade, during the 90-day postoperative period
2. Post-hepatectomy bile leakage (PHBL) evaluated using the definition provided by the international study group of liver surgery (ISGLS), and classified respectively according to severity grade, during the 90-day postoperative period
3. Post-hepatectomy liver hemorrhage (PHH) evaluated using the definition provided by the international study group of liver surgery (ISGLS), and classified respectively according to severity grade, during the 90-day postoperative period

Completion date
01/01/2022

Eligibility

Key inclusion criteria
Patients with cholangiocarcinoma undergoing the ALPPS procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Heidelberg
Surgery Clinic
Im Neuenheimer Feld 420
Heidelberg
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69120

Sponsor information

Organisation
Chirurgische Universitätsklinik Heidelberg

ROR
https://ror.org/05fe3fx56

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data of participants, including demographic data, and intraoperative and postoperative outcomes, will be provided anonymously upon the logical request, including requests for multicenter studies and collaborations, without limitation in the availability period. The data will be made available after evaluation of the study protocol and ethical approvals by the principal investigator Prof. Dr. med. Arianeb Mehrabi (arianeb.mehrabi@med.uni-heidelberg.de).

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2023	31/05/2023	Yes	No
Results article		28/11/2023	04/07/2024	Yes	No