Trial Description

Title

Effect of an interactive app on patient time to functional recovery (TFR) ongoing elective onco-logical liver resection (LR): The RECOLIV Trial – A Randomized Controlled Trial

Trial Acronym

RECOLIV

URL of the trial

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Brief Summary in Lay Language

Tumor diseases are among the most common diseases worldwide and the number of these is constantly increasing. Many of the affected patients inform themselves online about their treatment options and about experiences and evaluations with regard to the upcoming procedure in the corresponding clinic. At the same time, the information is becoming increasingly difficult to understand due to the increasing mass and technical terms. Due to the increasing number of treatments combined with increasing scarcity of resources, the treating physician also has less time with the patient. This can lead to frustration concerning patients and health care professionals.
In the past, the use of mobile technologies in healthcare as well as in the public health system has grown more and more in order to counteract these findings. Most clinics currently use informational brochures to inform patients about their illness and the further course of therapy. However, the majority of patients cannot use these adequately, as they are usually too extensive in the context of the diagnosis and the events that occur and are not adapted to the current stage of treatment. Information, checklists, process sheets and recommendations that are individually adapted to the therapy section could shorten the time to functional recovery after liver surgery. The app could also improve their satisfaction and quality of life.
The currently by many disciplines used clinical pathways primarily serve to standardize therapy processes and optimize them. Their benefits have been well researched, but patients are often not included in the individual process steps. For this reason, a clinical study will be carried out to investigate whether recovery or time to functional recovery after liver resection is shorter if patients receive information and recommendations about the therapy by usage of an interactive app.
The aim of this study is to investigate whether the time to functional recovery after oncological liver resection can be improved by using an interactive app on a personal mobile phone. The hypothesis that the usage of an interactive app reduces the time to functional after liver resection has to be confirmed.

Brief Summary in Scientific Language

Minimizing the time to functional recovery (TFR) is a primary goal after liver

resection (LR), as a shortened resumption of the preoperative activity is one of the major goals to prevent postoperative complications. The RECOLIV trial is a prospective superiority study with an experimental parallel group design with equal allocation, using two double-blinded randomized controlled arms to determine whether TFR can be reduced by usage of an interactive app with timely day per day information & recommendations after elective oncological LR compared to the standard of care without concomitant interactive app usage. While the primary endpoint is TFR a set of patient reported experiences (PREs) and outcomes (PROs), general and surgical variables as well as app usage data will be analysed to evaluate efficacy of both methods (standard care vs. standard of care & interactive app usage with timely day per day information and recommendation). The study focuses on the time of consent (preoperative period) until postoperative day (90) after primary LR.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00022159**
- Date of Registration in DRKS: **2020/09/24**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2020-608N , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C22 - Malignant neoplasm of liver and intrahepatic bile ducts**
- ICD10: **C78.7 - Secondary malignant neoplasm of liver and intrahepatic bile duct**
- ICD10: **C22.1 - Malignant neoplasm: Intrahepatic bile duct carcinoma**

Interventions/Observational Groups

- Arm 1: **Group A (Control group): Elective oncological LR according to the standard of care without inter-active app usage (app will provide basis information and will be used to record patient reported outcomes (PROs) and patient reported experiences (PREs)).**
- Arm 2: <style fontName='DejaVu Sans' isBold='true'>Group B (Experimental group): Elective oncological LR according to the standard of care and intervention via interactive app (timely day per day information & recommendations).</style>

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Time to functional recovery

Secondary Outcome

• Congruence of PRO regarding functional recovery compared to health care professional as-sessed outcomes
• Patient-reported quality of recovery (QoR-15)
• Health-related quality of life (HRQoL)
• Patient satisfaction
• General self-efficacy scale
• Pulmonary embolism
• Pulmonary infection
• Renal failure
• Delayed discharge time (DDT)
• Post-discharge health care consumption (PDHCC)
• Morbidity and mortality according to Clavien-Dindo classification at 90 days respectively comprehensive complication index (CCI)
• App usage data

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Chirurgische Klinik, Mannheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/02/01**
- Target Sample Size: **98**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

**Patients scheduled for elective oncological LR are eligible for inclusion.
Subjects matching the following criteria are eligible for inclusion into the clinical trial:**
• Primary or secondary liver malignancies
• Age equal or greater than 18 years
• Ability to understand the character and individual consequences of the clinical trial
• Owner a mobile phone (Android or iOS) and possession of an email address
• Written informed consent

Exclusion criteria

• Extrahepatic resection required based on preoperative imaging
• Significant cardiac or respiratory failure (ASA > 3)
• Child C liver cirrhosis
• Planned re-operation within 30 days after index operation
• Impaired mental state or incompetence of understanding the German language (no fluent German language speakers)
• Expected lack of compliance

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***

Reason, if Reason for Recruiting Stop "Other": **[---]***

- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*