aCcelerated erAS carE for minor and major liver surgery: the CHASE liver study

Published: 24-07-2024
Last updated: 22-02-2025

The aim of this study is to investigate the feasibility and safety of an accelerated protocol for patients undergoing liver surgery compared to a retrospective cohort of patients who followed the standard ERAS care for liver surgery. In this...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON56942

Source
ToetsingOnline

Brief title
CHASE liver

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
Liver malignancies, Liver neoplasms, Liver tumors

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Vergoeding vanuit ziekenhuizen zelf

Intervention

Keyword: Accelerated Enhanced Recovery, Enhanced Recovery After Surgery, Liver Neoplasms

Outcome measures

Primary outcome

Rate of the successful and safe application of the accelerated recovery protocol for patients undergoing elective liver surgery. Success rate (feasibility) will be measured in length of hospital stay (LOS). Success is defined as discharge on POD1 after a minor liver resection and on POD2-3 after major liver resection discharge. Safety will be measured with rate of readmission and serious adverse events (Clavien Dindo >=3b) within 90 days postoperatively.

Secondary outcome

• Postoperative complications within 90 days

• Postoperative mortality within 90 days

• Difference between achievement of functional recovery and actual discharge date

• Patient satisfaction evaluation form

• Demographic parameters

• Disease related demographics

• Comorbidities

Study description

Background summary

Throughout the years, there has been a rapid change in the perioperative protocols and procedures surrounding liver surgery. Upon the introduction of the Enhanced Recovery After Surgery (ERAS) program in Western countries, an improvement in postoperative outcomes was seen. Nowadays, researchers focus on further improving the current standard ERAS programs enabling an accelerated version hereof.

Study objective

The aim of this study is to investigate the feasibility and safety of an accelerated protocol for patients undergoing liver surgery compared to a retrospective cohort of patients who followed the standard ERAS care for liver surgery. In this protocol, patients undergoing liver surgery will be discharged within respectively 24 (minor liver resection) or 48-72 hours (major liver resection) after surgery.

Study design

This study is an investigator-initiated, multi-center prospective study. This feasibility study will compare 20 patients undergoing minor or major liver resections, whether or not combined with ablation, and treated according to the CHASE program with 20 patients of a retrospective cohort who followed the current standard ERAS protocol in the Maastricht University Medical Center+ (MUMC+). Patients will be screened, recruited and enrolled at Zuyderland Medical Center en MUMC+.

Intervention

Patients in this study will follow the CHASE protocol, which consists of a multidisciplinary approach aimed at optimizing the pre-, intra- and post-operative procedures surrounding elective liver surgery.
This accelerated recovery protocol focuses on three main factors: infusion management, pain management and truly minimally invasive surgery.

Study burden and risks

Patients included in this study will be guided and thoroughly informed about the procedures pertaining to CHASE. All procedures and protocols are divided in the preoperative phase, the perioperative phase and the postoperative phase. Other than an evaluation form (1x); provision of a limited array of pain medication; faster postoperative feeding and mobilization, included patients are not subjected to a greater burden when compared to standard protocol. Included patients are requested to arrange postoperative ambulant care for the first 24-hours after discharge. Potential pain and discomfort associated with surgery is not expected to be worse than in patients who are treated according

to the standard ERAS protocol.

Contacts

Public
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Geleen 6162 BG
NL
Scientific
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Geleen 6162 BG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Signed informed consent;
- Is >= 18 years <= 85;
- BMI <= 35 kg/m2;
- ASA I-III;
- Diagnosed with liver malignancy;
- Is scheduled to undergo elective laparoscopic liver resection, whether or not combined with ablation
- Readily available ambulant care provided by an adult family member for the first 24 hours after discharge;

- Proficient in Dutch language and writing;
- Patient is adequately reachable by phone.

Exclusion criteria

- ASA classification > 3;
- Subjects undergoing rehepatectomy
- Subjects who have limited mobility and/or need to be aided/assisted when mobilizing;
- Subjects with a history of active pulmonary infection, any other active infection, any uncontrolled medical disease;
- Subjects with (any form of) liver cirrhosis
- Subjects with a contraindication for oral NSAIDs;
- Subjects with a contraindication for spinal anesthesia;
- Subjects requiring parenteral nutrition prior to surgery;
- Subjects receiving an ostomy;
- Subjects who experience complications preoperatively;
- Subjects who are mentally incompetent, challenged or requiring aid with daily life activities.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-07-2024
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	10-02-2025
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86745.096.24