Accelerated 23-hour ERAS care for colon surgery.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52707

Source
ToetsingOnline

Brief title
CHASE

Condition

- Other condition
- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer

Health condition

Maagdarmstelselaandoening: colorectale kanker

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: geen

Intervention

Keyword: Bowel disease, Colorectal cancer, Enhanced recovery

Outcome measures

Primary outcome

Rate of the successful and safe application of the 23-hour accelerated ERAS protocol for patients undergoing elective colorectal surgery. Success rate (feasibility) will be measured in readmission rate and safety will be measured with rate of serious adverse events (Clavien Dindo >=3b). Success rate (feasibility) will also be measured in percentage of patients who were not able to be discharged after 23 hours.

Secondary outcome

• Demographic parameters

• Disease related demographics

• Comorbidities

• Postoperative complications within 30 days

• Postoperative mortality within 30 days

• Short Nutritional Assessment Questionnaire (SNAQ)

• Groningen Frailty Index (GFI)

• Patient satisfaction evaluation

Study description

Background summary

Throughout the years, there has been a rapid change in the perioperative protocols and procedures surrounding colorectal 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.
By improving perioperative recovery and care protocols, patients who undergo elective colorectal surgery could potentially benefit for faster hospital discharge without additional risk for postoperative complications.

Study objective

The aim of this study is to investigate the feasibility and safety of a 23-hour accelerated ERAS protocol for patients undergoing colorectal surgery. In this accelerated ERAS protocol, patients undergoing colorectal surgery will be discharged within 23 hours after surgery.

Primary Objective:
To assess the successful and safe application of the 23-hour accelerated ERAS protocol for patients undergoing colorectal surgery.

Secondary Objective(s):
• Postoperative outcomes, including morbidity and mortality within 30 days;
• Patient experience and satisfaction.

Study design

This study is an investigator-initiated, single-center prospective feasibility study. This feasibility study will compare 110 consecutive patients following the accelerated ERAS program to 110 most recent patients of a retrospective cohort who followed the current standard ERAS 1.0 protocol in Zuyderland Medical Center (zie document *Colorectaal Chirurgie Medisch ERAS*). A case-matched analysis will be performed.

Intervention

Patients included in this study will follow the 23-hour accelerated ERAS perioperative protocol which consists of a multidisciplinary approach focusing on optimizing the pre-, intra- and postoperative procedures surrounding an elective colorectal surgery.

This protocol for accelerated recovery and care focuses on three main contributors: fluid management, paint control and truly minimally invasive surgery.

Study burden and risks

A benefit of participating in this study is that this study provides an innovative and enhanced form of perioperative care in colorectal surgery. All procedures surrounding preoperative screening, preoperative preparing, anesthesia, surgery and postoperative care are optimized. Providing the best combination of circumstances for the participant. Hopefully reducing the admission length from 4 days to 1 day. All without compromising the safety of the patient. During the study, all participants are closely monitored and have a dedicated staff readily accessible to any questions and possible in-hospital evaluation.
Very few risks are associated with the participation of this study as patients who choose to participate will not be subjected to new treatments, rather a new protocol and order of said treatments. Participants will be closely monitored throughout the study, and will only be discharged if deemed safe. Though the risks are kept to a minimum, there is a small chance of the development of postoperative complications after discharge.

Contacts

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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;
• Is ASA III and diagnosed with (non-complicated) colorectal cancer
• Is scheduled to undergo elective laparoscopic colorectal surgery (right or left hemicolectomy, transvers colon resection, recto-sigmoid resection with primary anastomosis;
• Primary anastomosis is performed intracorporeally;
• Uncomplicated operation;
• Readily available ambulant care provided by an adult family member for the first 24 hours after discharge;
• Patient is adequately reachable by phone.

Exclusion criteria

• ASA classification > 3;
• 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 a contraindication for oral NSAIDs;
• Subjects with a contraindication for spinal anesthesia;
• Subjects requiring parenteral nutrition prior to surgery;
• Subjects scheduled to undergo lower rectal resections (TaTME, APR);
• 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:	Recruiting
Start date (anticipated):	08-06-2020
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	11-06-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-04-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-08-2021

Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	28-08-2022
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Not approved Date:	26-02-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-09-2024
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	NL71804.096.19