ULTRA-ERAS: discharge after 24hours after colorectal surgery, a pilot study

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The aim of the study is to assess if hospitalization can be reduced with the use of an early discharge protocol, named *ULTRA-ERAS*, in combination with tele monitoring in patients in elective colorectal surgery

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

Summary

ID

NL-OMON56276

Source
ToetsingOnline

Brief title
ULTRA-ERAS

Condition

- Other condition
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
darmaandoening; tumoren/diverticulitis

Health condition

postoperatieve zorg

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Onderzoeksfonds Antonius ziekenhuis

Intervention

Keyword: Colorectal, discharge, ERAS

Outcome measures

Primary outcome

Clavien Dindo >=3 complication rates (%) and initial length of stay (days)

Secondary outcome

success rate of *ULTRA-ERAS* (defined as <24hr length of stay), Total 30d LOS

(incl. readmission), 30d complication rate, readmission rates (%), 30d

mortality (%), patient satisfaction two weeks after hospitalization measured by

5-likert scale questionnaire, employee satisfaction halfway and after last

inclusion of pilot study measured by 5-likert scale questionnaire and

semi-structured interviews

Study description

Background summary

Over the last decade, Enhanced Recovery After Surgery (ERAS) protocols are widely integrated in abdominal surgery. This improved the procedures from a medical, financial and logistical perspective. Procedures such as cholecystectomy and bariatric surgery have already been shown to be successfully performed in combination with discharge within twenty-four hours. Current literature suggests that length of stay after colorectal surgery could safely be further reduced, in carefully selected patients by following a clear and structured protocol. Reduction of length of stay might help reduce hospital costs and could increase bed capacity in future healthcare.

Study objective

The aim of the study is to assess if hospitalization can be reduced with the use of an early discharge protocol, named *ULTRA-ERAS*, in combination with tele monitoring in patients in elective colorectal surgery

Study design

Prospective pilot intervention study

Intervention

All included patients will be treated according to our ULTRA-ERAS protocol. This protocol aims for discharge within twenty-four hours. After discharge they will receive a telemonitoring app to monitor complaints and vital parameters for the first five days at home.

Study burden and risks

Participants will undergo colorectal surgery and follow the ULTRA-ERAS protocol, which aims at discharge <24 hours after surgery. Previous research has shown that <24hr discharge is safe compared to usual care (1-3). Although patients will be discharge approximately two to three days earlier than usual, we minimize burden and risk by including many checkpoints in our protocol during hospitalization, thereby ensuring patient safety. Patients risk after discharge will be minimized by ensuring a 24/7 telephonic availability in-hospital nurse consultation and digital registration of complaints and vital parameters trough a mobile app.

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

- Elective minimal invasive right/left/hemicolectomy, ileocoecal or sigmoidal resection
- Uncomplicated procedure at sign-out
- Both benign and malignant indications for surgery
- Age <=80 years
- ASA score I or II
- Complete understanding of procedure and compliance
- A person at home during the first four days and living in a non-public living space (such as Leger des Heils)
- Lives within a half hour travel radius to the hospital and owns transportation to hospital

Exclusion criteria

- Anti-coagulants which require bridging
- Insulin dependent diabetes
- Multi-visceral resections
- Perioperative adhesiolysis, presence of abscess or need for enterostomy
- Perioperative conversion
- Perioperative placement of drains or gastric tubes
- cT4 tumours
- Lives in a public living space (such as Leger des Heils)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-03-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	19-01-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL81715.100.22