Improving compliance to the ERAS care pathway through improving patient participation by using eHealth

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON52407

Source
ToetsingOnline

Brief title
ERAS APPtimize

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal, eHealth, ERAS, surgery

Outcome measures

Primary outcome

The primary outcome is the overall compliance to the ERAS protocol measured as a mean of the percentages of the single ERAS protocol elements which patients are actively involved in.

Secondary outcome

Postoperative data < 30 days

• Length of hospital stay: continuous variable, measured in days

• Complications - major: ordinal variable, Clavien Dindo Classification of surgical complications (III-V)

• Complications - minor: ordinal variable, Clavien Dindo Classification of surgical complications (I-II)

• Overall morbidity within the first 30 days postoperative

• Reoperations: dichotomous variable, Yes/No

• Readmission <30 days: dichotomous variable, Yes/No

• In-hospital mortality: dichotomous variable, Yes/No

Gastrointestinal

• Tolerate solid food: continuous variable, measured in days until tolerate solid food

• Absence of nausea: continuous variable, measured in days until absence of nausea

• Passage of first flatus: continuous variable, measured in days until first flatus

• Passage of first stool: continuous variable, measured in days until first stool

• Weight - preoperative: continuous variable, measured in kilograms

• Weight - at discharge: continuous variable, measured in kilograms

Activity

• Mean preoperative physical activity: continuous variable, measured as a mean of steps per day during 1 week preoperative

• Postoperative physical activity: continuous variable, daily measured amount of steps per day until 3 weeks postoperative

• Fatigue: measured with the multidimensional fatigue inventory (Dutch: MVI-20) consisting of ordinal variables

Pain

• Perceived pain daily postoperative - discharge: continuous variable, daily measured post-operatively until discharge the visual analogue scale (VAS) 0-10

• Compliance with intake of (pain) medication: dichotomous variable, Yes/No

PROMS

• General quality of life: measured with the EQ-5D-5L questionnaire consisting of ordinal variables

• Gastro-intestinal quality of life: measured with the GIQLI questionnaire

consisting of ordinal variables

• Physical Activity: measured with the short International Physical Activity

Questionnaire (Dutch: INTERNATIONALE LICHAMELIJKE ACTIVITEITEN VRAGENLIJST)

consisting of continuous variables

• Patient satisfaction questionnaire: measured with a self-developed patient

satisfaction questionnaire consisting of ordinal variables.

Study description

Background summary

Perioperative care within colorectal surgery is systematically defined in the *Enhanced Recovery After Surgery* (ERAS) program. This program aims to improve perioperative care in a multimodal way to ensure early but safe release from the hospital. Adequate compliance to the elements of the ERAS protocol is multifactorial with room for improvement through patient involvement, which will enhance the post-operative outcomes such as length of stay in hospital.

Study objective

The aim is to improve compliance to the ERAS protocol. Therefore an application for smartphone will be developed to be used by the patient undergoing colorectal surgery. Objective of this study is to generate evidence that a mobile app can activate and stimulate a patient resulting in improved compliance to the ERAS protocol.

Study design

Multicentre randomized controlled trial

Intervention

The intervention in this study is a mobile application offering the ERAS-care pathway in a new way to patients undergoing colorectal surgery. The use of the application should enhance compliance to selected elements of the ERAS protocol. Based on the date of surgery, a timeline is generated within the application. Information or activities from the ERAS protocol will become available in the application when relevent. They are brought to the user's attention with pushnotifications. Besides informing patients and motivating

them to participate in their own care pathway, the app has a function in registering study outcomes, because after an item has been brought to the attention of the user, feedback is requested throug the application.

Study burden and risks

Both the control group as well as the intervention group will receive care conform the current standard. The only difference is the use of the app within the intervention group, therefore no additional risks are associated with participation in this trial. Burden of participation is restricted to the completion of four different questionnaires.

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

Individuals scheduled to undergo colorectal surgery due to: Inflammatory bowel disease, or colorectal cancer
Adults >18 years of age
Possession of a smartphone operated with iOS 9.0 and up or Android 8.0 and up

Exclusion criteria

Palliative surgery or surgery with additional radio- or chemotherapy
Severe comorbidity which could complicate the postoperative course
Patients with a Karnofsky score <=40
Incompetence of understanding the Dutch language
Visual impairment, unless well corrected with visual aids
Physical disabilities limiting the use of a mobile application, such as Parkinson*s disease
When pre-operatively is estimated that following the ERAS protocol postoperative is not feasible
Multiple organ resection

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2019
Enrollment:	164
Type:	Actual

Medical products/devices used

Generic name:	ERAS-APPtimisation;a patient centered mobile application to accompaniate patients undergoing colorec
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	02-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29410
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63874.018.17
OMON	NL-OMON29410