Monitoring Early Discharge After coLon surgery

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*Evaluate whether patients who are discharged early and are continuously monitored recover just as safely at home as they do in the hospital.**Evaluate whether complications can be detected in a timely manner by using continuous vital signs and...

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

Summary

ID

NL-OMON50289

Source
ToetsingOnline

Brief title
MEDAL-C

Condition

- Gastrointestinal conditions NEC

Synonym
Colon surgery for benign and malignant diseases, resection for benign and malignant colon pathology.

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Gesponsord door het JBZ (via de afdeling innovatie & implementatie)

Intervention

Keyword: colorectal surgery, early discharge, home recovery, remote monitoring

Outcome measures

Primary outcome

Successful application of early discharge and home recovery in patients after colorectal surgery

Secondary outcome

Number of patients with postoperative complications within 30 days of surgery

*Number of contact moments with patient as a result of measurements and/or questionnaires"

Number of patients who die within 30 days of surgery

Patient satisfaction regarding the experiences of home recovery 5 days after surgery

Study description

Background summary

Colon cancer is one of the most common types of cancer in the Netherlands and is expected to continue to rise. The increased demand for healthcare translates into a high workload, longer waiting times and a lack of capacity in the hospitals. One way to still deliver the growing need for care is through affordable innovations that allow optimal use of hospital capacity.

The aim of the Jeroen Bosch Hospital is to provide care that best suits the patients, within the aforementioned boundaries . This research is a new initiative with which the Jeroen Bosch Hospital (JBZ) aims to further reduce length of stay after colorectal surgery. This aim is in line with society's desire to provide *the right care in the right place at the right time*. It is also desirable that a patient continues to recover as far as possible in their own environment, since there is increasing evidence that patients recover more pleasantly and more quickly in a trusted environment.

Allowing patients who cope well with the operation and monitoring them from home will (possibly) reduce the length of stay in the future, while patients receive equally good quality treatment. When this study produces positive results, namely evidence that early discharge in combination with home recovery is safe, it will be introduced into clinical practice as soon as possible.

Study objective

Evaluate whether patients who are discharged early and are continuously monitored recover just as safely at home as they do in the hospital.
Evaluate whether complications can be detected in a timely manner by using continuous vital signs and digital questionnaires
Evaluate whether patients recovering at home are satisfied with the treatment offered

Study design

single center, interventional, prospective study

Intervention

participants are dismissed earlier and recover at home where they are continuously monitored using data from smart wearable sensors and digital questionnaires.

Study burden and risks

Failure to timely detect complications after bowel surgery in the home environment.
Allergic reactions to wearing the sensors
Possible stress as a result of home recovery and self-management
General discomfort while wearing the sensors (similar to wearing a watch)

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 consent form;
• Is >= 18 years <= 80;
• BMI <= 35 kg/m2;
• WHO performance status 0 - 1
• Has been diagnosed with uncomplicated colorectal malignant tumor (eg, colon carcinoma) or benign abnormality (eg, chronic diverticulitis)
• Is planned to undergo elective laparoscopic or robotic assisted colorectal surgery (ileocecal resection, (extended) right or left hemicolectomy, transverse colon resection, sigmoid and recto-sigmoid resection) with primary anastomosis;
• Uncomplicated course of the perioperative and immediate postoperative period;
• Available ambulatory care provided by an informal caregiver or adult family member during the recovery process;
• The patient has direct access to transport 24 hours a day;
• Patient stays within 35 km of the hospital;
• The patient (or family member) has a smartphone with mobile data and digital skills;
• The patient (or family member) is easily reachable by telephone.
• Concerned caregiver or adult family member must be competent to perform prescribed actions.

Exclusion criteria

• WHO-performance status >1
• Patients with a history of active lung infection, any other active infection, an uncontrolled medical condition
• Patients with a contraindication to oral NSAIDs;
• Patients requiring parenteral nutrition prior to surgery;
• Patients scheduled to undergo lower rectal resections;
• Patients who receive a stoma;
• Patients experiencing preoperative complications;
• Patients who are mentally incompetent, challenged or need help with daily activities.
• Patients experiencing complications per surgery
• If the operator or primary care provider decides that the patient cannot safely be discharged early. This can also be decided after the patient has been included in the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2022
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Radius PPG and Radius T
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-12-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-02-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL79338.028.21