Peri-operative (Continuous) Remote Patient Monitoring of Patients Undergoing Major Gastrointestinal Surgery: a Feasibility Study

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The aim of this study is to determine the feasibility of perioperative (continuous) remote patient monitoring using Ehealth devices and a daily questionnaire in patients undergoing major gastrointestinal surgery. Additionally, to determine (early)...

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON52280

Source
ToetsingOnline

Brief title
Peri-operative Box

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatobiliary neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Malignant neoplasms of the gastrointestinal tract; Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Philips

Intervention

Keyword: Ehealth, Gastrointestinal surgery, Montoring, Postoperative complications

Outcome measures

Primary outcome

To determine the feasibility (practical usability, technical, data quality) of perioperative (continuous) remote patient monitoring of patients undergoing major gastrointestinal surgery.

Secondary outcome

1. To investigate (early) determinants (vital parameters, questionnaire answers) of postoperative complications

2. To compare the number of alarms in continuous remote patient monitoring and the number of alarms during the standard of care

3. To determine the usability and feasibility of a daily questionnaire to detect postoperative complications

4. To investigate patient satisfaction of care using (continuous) remote patient monitoring

Study description

Background summary

Complex gastrointestinal surgery is associated with high incidence of complications, up to 60% depending on the type of surgery. With the increasing age these types of surgery (e.g., colectomy, esophagectomy) are performed more

frequently. Early detection of deterioration of patients after surgery and subsequent early intervention could lead to less morbidity on short- and long term. For early detection, (continuous) remote patient monitoring using Ehealth devices has shown potential. However, the use of (continuous) monitoring of vital parameters in clinical practice is still in its infancy. Therefore, this study focuses is a feasibility study to the use of perioperative remote patient monitoring using a wearable device for continuous monitoring together with other Ehealth devices and questionnaires for early detection of abnormal postoperative recovery, implying possible adverse events.

Study objective

The aim of this study is to determine the feasibility of perioperative (continuous) remote patient monitoring using Ehealth devices and a daily questionnaire in patients undergoing major gastrointestinal surgery. Additionally, to determine (early) signs (e.g., vital signs, questionnaire answers) of postoperative complications. Ultimately, this should lead to alterations in perioperative care to improve patients care and surgical outcomes.

Study design

This is a monocenter feasibility study, during this study patients undergoing major gastrointestinal surgery are using CE-marked Ehealth devices for (continuous) remote patient monitoring. Alongside these devices patients will be asked to fill-out a the MD Anderson Symptom Index (MDASI) questionnaire supplemented with the Dutch Postoperative Gastrointestinal Status Scale (DPGSS), concerning their health-status and recovery every day. The study consists of an observational study design, therefore all measurements and questionnaires will be blinded until the end of a patients study period, thus no clinical decisions are taken based on the measurements or questionnaire answers. The study period will be starting 4 days before admission until 7 days after discharge.

Intervention

Patients who consent to take part in the study will receive a Healthdot device: a thorax-located patch which continuously monitors heart rate, respiratory rate, activity, and posture. The monitoring starts up to 4 days before surgery and takes until the 14th day after discharge. Additionally, in the out-of-hospital setting before and after admission, patients receive a *Box* with eHealth devices to monitor all vital signs twice a day. During phase I of the study the measurements are blinded, thus no clinical decisions are taken based on the measurements. In phase IIa, an algorithm based on the modified early warning score (MEWS) is used, during phase IIb an AI algorithm based on the data obtained during phase I, is used to alarm nurses of abnormal vital

signs.

Study burden and risks

This study aims to pave the way for future studies and ultimately implementation of Ehealth in perioperative care leading to improved surgical outcomes, reduced workload on the surgical ward and enchanced patient satisfaction. The Box consists of CE-marked devices used in this study are non-invasive, easy-to-use and electrically safe, therefore the risk of using the devices is very limited. The study has no benefits for participants, since measurements and questionnaire answers are blinded for healthcare professionals, and therefore no medical decisions are made based on the measurements or daily questionnaire answers. Participation requires commitment, since participants need to wear a Healthdot, perform vital sign measurements twice a day and answer a questionnaire every day for the study period. Furthermore, participants have to fill out a questionnaire at the end of the study. This study does not present potential benefits for participating patients, however this study is an important first step for future studies and ultimately implementation of remote patient monitoring to enhance perioperative care and oucomes. We therefore believe this study is ethically justified.

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

a) Age 18years and older;
b) Admitted for major gastrointestinal surgery;
c) Predicted hospital stay of >= 3 days;
d) Elective surgery;
e) Curative intended surgery;
f) Basic understanding of smartphones and eHealth;
g) Being in possession of a smartphone;
h) Working Wifi-network at home or 4G-bundel.

Exclusion criteria

a) Cognitive disorders;
b) Not able to understand Dutch (written and/or verbally);
c) Not able to work with eHealth and/or smartphones;
d) Skin problems or wounds in the area of Healthdot;
e) Known allergy for the adhesive used in the Healthdot;
f) Palliative intended surgery or salvage surgery.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-04-2022
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Philips Healthdot;Withings Move;Withings;Body;Withings BPM Connect;Withings Thermo
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-06-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL75463.058.22