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Use of surgical pathways to improve patient recovery following surgery on the stomach /intestines

Submission date
18/05/2022

Recruitment status
No longer recruiting

Registration date
16/06/2022

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Enhanced Recovery After Surgery (ERAS) is a program designed to reduce dysfunction after surgery and enable the recovery of the patient as soon as possible. Patients are eligible for inclusion in this study if they are undergoing major colorectal surgery, which traditionally includes a prolonged rehabilitation period after surgery. The aim of this study is to establish an ERAS protocol for patients undergoing colorectal surgery based on previously standardized evidence-based enhanced recovery programs (ERPs). The objective is to monitor the impact of ERAS protocol on death rates, length of stay and complications after surgery. It is expected that the implementation of an ERAS protocol will reduce the cost of colorectal surgery, improve quality of life, reduce patient length of stay and improve patient outcomes.

Who can participate?
Patients undergoing major colorectal surgery

What does the study involve?
Participants will be asked to follow a care pathway for colorectal surgery. The pathway from pre-surgery to recovery is specifically designed to help patients heal more quickly, eat and move sooner, and optimally control pain. Studies show that this program helps patients feel better and recover more quickly. Participants are asked to follow the guidelines described within the ERAS handbook. This includes stopping smoking 4 weeks before surgery, eating optimally, getting some exercise, early return to diet after surgery, and getting out of bed and moving (with help) as soon as possible after surgery.
The Surgery care team in Huntsville (Huntsville District Memorial Hospital site of Muskoka Algonquin Healthcare) will review the Enhanced Recovery steps with participants before their surgery, during their hospital stay, and before they go home. The main steps involved in this care pathway are pre-admission counselling, fluid and carbohydrate loading and early mobilization. Participants will answer a questionnaire which will include questions regarding patient outcomes and complications after surgery. Data will be collected for 15-30 days after the surgery. Participating in this study involves providing feedback and allowing data to be included in the study. Names and any personally identifying information will not be included with the study

data. For research purposes, participants will be assigned a random identification. When publishing the results of this study participants name and information will be grouped with other participants to ensure identification is not possible.

What are the possible benefits and risks of participating?
The only risk involved in participating in this study would be inadvertent sharing of data, but patient names will not be linked to study data so this risk is minimal. The benefit of participating is in showing other similar sized institutions that this program is effective and manageable in a small rural facility.

Where is the study run from?
Muskoka Algonquin Healthcare (Canada)

When is the study starting and how long is it expected to run for?
January 2015 to November 2017

Who is funding the study?
Northern Ontario Academic Medical Association (Canada)

Who is the main contact?
Dr Hector Roldan, hector.roldan@mahc.ca

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Enhanced Recovery After Surgery reduced length of stay after colorectal surgery in a small rural hospital in Ontario

Study objectives
To determine if Enhanced Recovery After Surgery (ERAS) procedures can be implemented in a small rural hospital having a positive effect on patient outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/04/2015, Laurentian University Research Ethics Board (935 Ramsey Lake Road, Sudbury, ON, Canada; +1 (0)705 675 1151; ethics@laurentian.ca), ref: 2015-02-02

Study design
Prospective observational single-centre study

Primary study design
Observational

Secondary study design
Quality improvement study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Not available online, please use contact details to request a participant sheet

Health condition(s) or problem(s) studied
Implementation of ERAS for colorectal surgery

Interventions
ERAS preoperative procedures that focus on patient engagement and optimal preparation for their surgical procedure in four key areas; breathing (smoking cessation), movement (exercise), nutrition and expectations (clear surgery date). Intraoperatively the patient is maintained at the ideal anaesthesia depth, have active warming, and have goal-directed fluid therapy throughout the procedure, particularly for high-risk patients. They are risk-stratified for nausea and vomiting and are given pre-emptive medication accordingly. Postoperatively pain is managed with multi-modal therapy, minimizing opioid use – recognizing that narcotic use is a rate-limiting step in patients regaining bowel function, which directly influences length of stay and can result in further complications. Nasal gastric tubes, bladder catheters, drains and IV fluids are used sparingly and removed as soon as possible. Enteral feeding and early mobility are introduced as soon as feasible after surgery.

All eligible patients were included in this study as ERAS was implemented as standard of care.

Intervention Type
Behavioural

Primary outcome measure
Length of stay for surgery (nights in hospital) collected from patient chart

Secondary outcome measures
1. Total number of ileus compared to retrospective data: yes or no (present or not) based on surgeon assessment and notes up to 30 days post-operative
2. Total number of wound infections compared to retrospective data: yes or no noted in the patient chart by the nurse caring for the patient up to 30 days post-operative
3. Total number of dehiscence compared to retrospective data: yes/no noted in chart up to 30 days post-operative
4. Total number of deep vein thrombosis compared to retrospective data: yes/no noted in chart up to 30 days post-operative
5. Total number of patients with anastomotic leak compared to retrospective data: yes/no noted in chart up to 30 days post-operative
6. Total number of patients who develop pneumonia compared to retrospective data measured using patient charts up to 30 days post-operative
7. Total number of patients reporting/demonstrating nausea/vomiting compared to retrospective data noted in patient chart until discharge
8. Total number of patients experiencing urinary retention compared to retrospective data: yes /no noted in the patient chart until discharge
9. Total number of patients experiencing wound infection - yes/no noted in chart up to 30 days post-operative
10. Total number of patients experiencing readmission: yes/no noted in chart up to 30 days post-operative
11. Pain assessed using a visual analog scale at baseline (within 3 hours of surgery) and on each day in hospital am and pm until discharge

Overall study start date

02/01/2015

Completion date
27/11/2017

Eligibility

Key inclusion criteria
All patients undergoing gastrointestinal surgery for cancer, fistula, lesion repair, diverticulitis, polyp repair, prolapse

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
47

Total final enrolment
47

Key exclusion criteria
Significant complications postoperatively as noted by the physician

Date of first enrolment
01/05/2015

Date of final enrolment
16/11/2017

Locations

Countries of recruitment
Canada

Study participating centre
Muskoka Algonquin Healthcare
100 Frank Miller Drive
Huntsville
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.mahc.ca/en/index.aspx

Funder(s)

Funder type
Other

Funder Name
Northern Ontario Academic Medical Association

Results and Publications

Publication and dissemination plan
The researchers aim to publish this study in an appropriate peer-reviewed journal. They have also disseminated the results locally through standard media, and internally within a monthly newsletter.

Intention to publish date
01/08/2022

Individual participant data (IPD) sharing plan
Data is presently stored deidentified on our hospital hard drive in a file specific for this study. Permission to access that file is granted to Lisa Allen (Research Coordinator) and the principal investigator (Hector Roldan, hector.roldan@mahc.ca), who would be the contact for data sharing requests. The information stored in the research file includes research ID and outcomes noted in addition to the procedure they had completed. The researchers did not store other

demographics or potentially identifying information. They would share data for those interested in assessing larger data sets and would need ethics approval and assurance that small data cells would be presented as grouped to prevent inadvertent reidentification. Patient consent for inclusion in the study and data access was collected from each participant. The ethics submission indicates that data will be stored in this matter indefinitely, or as long as it can be maintained. Participants are assigned a research ID when they sign their consent form. All data used for this study is then attributed to that research ID.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		25/03/2022	31/05/2023	No	No