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The effect of the enhanced recovery after surgery (ERAS) program on length of stay among abdominal surgery patients at Mbarara Regional Referral Hospital, Uganda

Submission date
03/03/2020

Recruitment status
No longer recruiting

Registration date
09/03/2020

Overall study status
Completed

Last Edited
09/03/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A laparotomy is a surgical procedure involving a large incision through the abdominal wall to gain access into the abdominal cavity.
Enhanced recovery after surgery (ERAS) is a model of care for elective surgery that combines elements of care to form a structured pathway to decrease physical issues after surgery, which may lead to complications and death during and after the surgery, and increase the length of hospital stay. The main goal of ERAS is to enhance the recovery of patients and thus reduce the length of hospital stay, minimize cost, complications and readmission rates after surgery. ERAS is being safely implemented across the world. But it has not been implemented in the low-income African countries. There is need to examine the feasibility of the ERAS in our settings. Studies done outside Uganda (Egypt and South Africa) have demonstrated that ERAS program can be feasible and yields favorable outcomes in patients. This study will help to improve on the management and treatment of patients before, during and after operation.

Who can participate?
Patients 18 years of age and above, scheduled for non-emergency laparotomy.

What does the study involve?
Participants will be randomly allocated to receive the ERAS care pathway or treatment as usual for up to 14 days after their surgery.

What are the possible benefits and risks of participating?
The benefits of participating: This study will help to improve on the management and treatment of patients before, during and after operation. Participants will also be given counselling and health education about their sickness.
The Risks: Minimal to mild pain may be experienced during mobilization after operation.

Where is the study run from?
Mbarara regional referral Hospital, Uganda

When is the study starting and how long is it expected to run for?
June 2017 to August 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT03665376

Secondary identifying numbers
Nil known

Study information

Scientific Title

Feasibility and efficacy of Enhanced Recovery After Surgery (ERAS) on length of stay among laparotomy patients at Mbarara Regional Referral Hospital, Uganda

Acronym
ERAS

Study objectives
1. Is the ERAS program feasible at MRRH?
2. Is there any difference in the length of post-operative hospital stay that can occur with the implementation of ERAS?
3. Which perioperative complications may arise during implementation of ERAS in laparotomies?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2017, Faculty of Medicine Research Committee (FRC) at Mbarara University of Science and Technology (MUST) (P.O. Box 1410, Mbarara – Uganda; +256-485-433-795; sec. rec@must.ac.ug), ref: MUREC 1/7

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Laparotomy

Interventions
Experimental: ERAS arm
Preoperative: Counseling and education about the ERAS program; Oral intake until 6 hours before the surgery; Carbohydrate drinks load; No mechanical bowel preparation; Antithrombotic prophylaxis (Tinzaparin 3500 IU) Intraoperative: Spinal anaesthesia (15 mg hyperbaric Bupivacaine + 200mcg intrathecal Morphine); Intravenous Ceftriaxone 2g, Metronidazole 500mg / Gentamycin 160mg, Ondansetron 8mg and Dexamethasone 8mg; Crystalloid fluid 10 to 20ml /Kg; Adrenaline 200mcg in each 500 ml of intravenous fluid; Avoidance of abdominal drains; Postoperative: Early oral intake; Nasogastric tube and urinary catheter removed immediately

after the surgery; Early enteral nutrition; Chewing gum for 2 to 4 hours after surgery; Oral sips 8 hours postoperatively; Intravenous fluids discontinued at four hours after transfer to the ward.

No Intervention: Control arm
Preoperative: No carbohydrate drink loads, no antithrombotic prophylaxis; Mechanical bowel preparation as needed; Spinal anaesthesia, fluid therapy and antibiotherapy done according to standard hospital practice. The urinary catheter and drains were removed at the discretion of the surgeon. Postoperative: Enteral feeding delayed by the auscultation of bowel sounds. The standard hospital practices involve keeping active the nasogastric tube, fasting patients postoperative, strict bed rest… Pain control was managed with medication of choice by surgeon and anesthesiologist.

Numbers for randomisation into groups were generated and kept in sealed envelopes. Neither the investigators nor the study participants were blinded.

Intervention Type
Procedure/Surgery

Primary outcome measure
Length of hospital stay from the day of surgical operation up to 14 days

Secondary outcome measures
1. Adverse events or death occurring during or 14 days after the surgical operation
2. Readmission rate measured as admission of a patient in the hospital within 14 days after discharge

Overall study start date
01/07/2016

Completion date
15/08/2017

Eligibility

Key inclusion criteria
1. 18 years of age and above
2. Scheduled for non-emergency laparotomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
33

Key exclusion criteria
1. Pregnancy
2. Admitted for emergency laparotomy, or had ASA physical status score greater than III
3. Scheduled for other surgery other than elective gastrointestinal laparotomy
4. Diabetic patients

Date of first enrolment
01/06/2017

Date of final enrolment
30/07/2017

Locations

Countries of recruitment
Uganda

Study participating centre
Mbarara regional referral Hospital
Kabale highway
Mbarara
Uganda
00256

Sponsor information

Organisation
Mbarara University of Science and Technology

Sponsor details
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Sponsor type
University/education

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http://www.must.ac.ug/

ROR
https://ror.org/01bkn5154

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request