

The effect of postsurgery exercise on recovery from colorectal cancer surgery

Submission date 17/02/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/06/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A transient postoperative ileus, a temporary disturbance in gastric and bowel motility following surgery, is recognized as an expected outcome of any major abdominal surgery including colon and rectum. Delayed recovery from the surgery would also delay the initiation of subsequent therapies. Therefore, it is important to find modality which may reduce postoperative ileus and enhance recovery from the surgery as early as possible. In recent years, the Enhance Recovery after Surgery (ERAS) aimed at improving before and after surgery care and decreasing postoperative complication, has been used extensively. Techniques include optimal pain control by epidural (anaesthetic drug injected in spine) and local anaesthesia, minimally invasive techniques and aggressive post-operative rehabilitation, which include early feeding, removal of tube, early ambulation (walking). Although studies examined the safety, efficacy and effectiveness of this protocol on surgery outcomes including the length of hospital stay, these studies did not measure the effects of early ambulation separately. Therefore, the purposes of the current study are 1) to investigate the effects of post-surgery exercise on surgery outcomes including the length of hospital stay, time to flatus (passing wind) and time to first normal diet, 2) to investigate the association between surgery outcomes change in body measurements and fitness levels during recovery from surgery.

Who can participate?

Patients who are admitted to Severance hospital for stage 1-3 colon cancer can participate in the study. To take part you need to be aged 18 years or older, have a good understanding of Korean language and is willing to participate in the study.

What does the study involve?

Patients will be randomly allocated to control group (usual care) or exercise group. In the exercise group patients will undergo 1-15 minute exercise under the guidance of exercise therapist. Fitness will be measured before the surgery and one day before the hospital release.

What are the possible benefits and risks of participating?

Participants randomized to the exercise group will receive personalized exercise program while

they are staying at the hospital after the surgery.

All exercise is symptom limited and therefore if the patient feels pain or do not want to exercise, then he/she does not have to exercise. There are no known risks to participants.

Where is the study run from?

The study takes place at Severance Hospital located at Shinchon, Seoul, Korea

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

Patients were enrolled in the study between May 2011 to Feb 2012

Who is funding the study?

Ministry of Health and Welfare in Korean Government

Who is the main contact?

Dr Nam Kyu Kim

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Postoperative exercise reduced the length of hospital stay among stage 1 to 3 colon cancer patients: Randomized controlled trial of efficacy and safety of exercise protocol

Study objectives

Postoperative exercise will reduce the time of hospital stay, time to flatus and time to the first normal diet

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Ethics Review Board at Yonsei University College of Medicine, ref: 2004-2010-0147

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Stage I to III colon cancer

Interventions

Randomized into either an exercise or usual care group via minimization method.

Exercise group - The patient will undergo 1-15 minute exercise under the guidance of exercise therapist.

The other group will undergo usual care during their recovery from surgery.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. The length of hospital stay
2. Time to flatus
3. Time to the first normal diet

Secondary outcome measures

1. Fitness
2. Body composition

Measured before the surgery and one day before the hospital release

Overall study start date

01/03/2011

Completion date

01/03/2012

Eligibility

Key inclusion criteria

1. Stage 1-3 colon cancer
2. Aged between 18-70
3. Able to read and understand Korean language

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

20 patients in each group

Key exclusion criteria

1. Patient with recurrent cancer
2. Patient with body mass index (BMI) less than 18 kg/m² or over BMI 30kg/m²

Date of first enrolment

01/03/2011

Date of final enrolment

01/03/2012

Locations

Countries of recruitment

Korea, South

Study participating centre

134 Shinchon-Dong

Seoul

Korea, South

120-749

Sponsor information

Organisation

Yonsei University College of Medicine (Korea, South)

Sponsor details

c/o Nam Kyu Kim

Department of Surgery

250 Seongsan-ro

Seodaemun-gu

Seoul

Korea, South

120-752

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01wjejq96>

Funder(s)

Funder type

Government

Funder Name

National Research Foundation of Korea (NRF) (Korea, South) (No.2011-0004892)

Alternative Name(s)

, National Research Foundation (South Korea), NRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Korea, South

Funder Name

National R & D program for Cancer Control, Ministry of Health and Welfare, Republic of Korea (1120230)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration