

Effect of exercise on fitness in colorectal cancer survivors

Submission date 03/01/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/01/2014	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

Cancer has become a major public health problem in South Korea. Lifestyle factors determine the risk of colorectal cancer and the course of the disease. Studies have shown a strong link between the level of physical activity and the outcomes of colorectal cancer. Although observational studies have shown the link between physical activity and the physical fitness of colorectal cancer patients, there are few interventional studies which have shown these beneficial effects. Therefore, the aims of this study are to investigate the effects of a 6-week home-based exercise intervention on cardiovascular and musculoskeletal fitness and patients perceived bowel function in stage II-III colorectal cancer survivors.

Who can participate?

Patients with stage II-III colorectal cancer who have completed all standard cancer-directed therapy at least 4 weeks but no more than 2 years before the study.

What does the study involve?

Patients are randomly allocated to either the exercise group or the control group. Exercise group patients will be encouraged to walk more than 10,000 steps per day. A pedometer will be provided to count the steps. Patients will be provided with exercise DVDs, which consist of 30 minutes exercise using their own body weight, to be performed at home daily. Following each exercise session, participants will complete their exercise log, recording the daily steps, type of exercise and duration. Exercise group participants will visit the clinic three times during the 6 weeks. They will have two exercise education sessions, and the exercise trainer will make sure that patients are able to perform the exercise properly. Control group patients will be instructed to continue with their usual daily activities. The intervention period will be 6 weeks and assessments will be carried out before the start of the study and at 6 weeks.

What are the possible benefits and risks of participating?

All participants will receive exercise DVDs, a pedometer, exercise handouts, and the results of the clinical tests. There are no known risks to participants.

Where is the study run from?

Severance Hospital, Shinchon, Seoul, Korea.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study between August 2011 and October 2014.

Who is funding the study?
Ministry of Health and Welfare, South Korea.

Who is the main contact?
Professor Justin Jeon
jjeon@yonsei.ac.kr

Contact information

Type(s)
Scientific

Contact name
Prof Justin Jeon

Contact details
Shinchon-Dong
Seodaemun-Gu
Yonsei University
Seoul
Korea, South
120-749
+82 2 2123 6197
jjeon@yonsei.ac.kr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of a 6-week home-based exercise program on fitness in colorectal cancer survivors: a randomized controlled trial

Study objectives
The 6-week exercise intervention program will improve cardiovascular and musculoskeletal fitness and patients perceived bowel function in colorectal cancer survivors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Ethics Review Board at Yonsei University College of Medicine

Study design

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

Stage II to III colorectal cancer survivors

Interventions

Participants will be randomized into either an exercise or usual care group via minimization method.

1. The exercise group will receive a 6-week home-based exercise program. They will be encouraged to walk more than 10,000 steps per day (pedometer will be provided). In addition, patients will be provided with exercise DVDs, which consisted of 30 minutes exercise using their own body weight, to be performed at home daily. Following each exercise session, participants will complete their exercise log, recording the daily steps, type of exercise and duration. Exercise group participants will visit the clinic three times during 6 weeks. They will have two exercise education sessions, and the exercise trainer will make sure that patients are able to perform the exercise properly.
2. Participants in the control group will be instructed to continue with their usual daily activities.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Cardiovascular and musculoskeletal fitness measured by the 3-minute step test and push up test, respectively
2. Patient perceived bowel function measured by questionnaires

Secondary outcome measures

Quality of life measured by the Functional Assessment of Cancer Therapy - Colorectal (FACT-C) scale

Overall study start date

27/08/2011

Completion date

19/10/2014

Eligibility

Key inclusion criteria

1. Between 18 and 75 years of age
2. Histologically confirmed stage II to III colorectal cancer
3. Completed surgery, radiotherapy, and/or chemotherapy within 4-104 weeks prior to the study
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
5. Not planning extended absences in the 3 months subsequent to enrollment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

56 patients in each group

Key exclusion criteria

1. Existing evidence of recurrent or metastatic disease
2. Participation in regular physical activity (purposeful activity of at least a moderate intensity of 200 minutes or more a week)
3. Pregnant or planned to be pregnant within 6 months

Date of first enrolment

27/08/2011

Date of final enrolment

19/10/2014

Locations

Countries of recruitment

Korea, South

Study participating centre
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
Sedaemun-gu
Seoul
Korea, South
120-752

Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Government

Funder Name

National Research Foundation of Korea (NRF) (No.2010-0009048)

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

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