ISRCTN47234641 https://doi.org/10.1186/ISRCTN47234641

Effect of exercise on insulin resistance and adiponectin in colorectal cancer survivors

Submission date
20/04/2014

Recruitment status
No longer recruiting

Registration date
30/04/2014

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cancer has become a major public health problem in South Korea. The lifestyle factors are important determinants of colorectal cancer risk. Previous studies have shown a strong association between the level of physical activity and the outcomes of colorectal cancer. However, the effects of exercise on insulin resistance and adipocytokines in colorectal cancer patients still need to be investigated. The aim of this study are to assess the effects of a 12-week home-based exercise intervention on insulin resistance and adiponectin (the hormone produced by fat cells which influences the bodys response to insulin) in colorectal cancer survivors.

Who can participate?
Patients with stage II-III colorectal cancer, who have completed all standard cancer treatment at least 4 weeks earlier but no more than 2 years.

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. They will get exercise DVDs, will record their daily activities and will visit the clinic five times during the 12 weeks. Control group patients will be instructed to continue with their usual daily activities.

What are the possible benefits and risks or participating?
Participants allocated to the exercise group will receive the exercise DVDs, a pedometer, exercise hand outs, and results of clinical tests. There are no known risks to participants.

Where is the study run from?
Severance Hospital, Shinchon, Seoul (South 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 December 2014.

Who is funding the study?
Ministry of Health and Welfare (South Korea)

Who is the main contact?
Professor Justin Jeon
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of 12-week home-based exercise program on insulin resistance and adiponectin in colorectal cancer survivors: a randomized controlled trial

Study objectives
The 12-week exercise intervention program will decrease fasting insulin resistance and increase adiponectin 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)
Other

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 12-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. Level of fasting insulin will be measured by a chemiluminescence immunoassay
2. Adiponectin levels will be measured by an enzyme immunoassay kit
3. Insulin resistance will be estimated using the homeostatic model assessment of insulin resistance (HOMA-IR) index

Secondary outcome measures
1. hs-CRP will be measured by a latex-enhanced immunoturbidimetric assay using an ADNIA 1650 Chemistry system 2. TNF-a levels will be measured using a commercially available enzyme-linked immunosorbent assay
3. Chemerin levels will be measured by an enzyme immunoassay kit
4. Levels of fasting glucose, AST, ALT, GGT, TC, TG, HDL-C will be measured using an ADVIA 1650

Chemistry system
5. Physical fitness measured by the 30minute step test, 6-min walk test, chair stand and push up test
6. Quality of life measured by the FACT-C questionnaires

Overall study start date
27/08/2011

Completion date
31/12/2014

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. ECOG performance status of 0 of 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

Upper age limit
75 Years

Sex
Both

Target number of participants
56 patients in each group

Total final enrolment
123

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 month

Date of first enrolment
27/08/2011

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Korea, South

Study participating centre
134 Shinchon-Dong, Seodaemun-Gu, Yonsei University
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Sponsor information

Organisation
Yonsei University College of Medicine (South Korea)

Sponsor details
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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 - National R & D program for Cancer Control (Republic of Korea), Ref: 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017	23/10/2020	Yes	No