Physical ExeRcise Following Esophageal Cancer Treatment (PERFECT) Study: a randomized clinical trial

Published: 10-12-2014
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Primary Objective: - To investigate whether a 12-week exercise intervention increases HRQoL in patients after curatively intended EC surgery compared to a usual care control group.Secondary Objective(s): - To investigate whether a 12-week exercise...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON47661

Source
ToetsingOnline

Brief title
PERFECT study

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
cancer of the esophagus, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: world cancer research fund (WCRF)

Intervention

Keyword: esophageal cancer, health related quality of life, physical exercise

Outcome measures

Primary outcome

Health-related quality of life.

Secondary outcome

- Functional wellbeing and symptoms

- Esophagus-specific QoL

- Fatigue

- Anxiety and depression

- Diet

- Sleep quality

- Physical activity

- Body composition

- Work ability

- Blood markers (e.g. inflammatory markers)

- Physical fitness (cardiorespiratory fitness, muscle strength)

- Cancer recurrence

- Overall survival

Study description

Background summary

Patients after esophageal cancer surgery are often fatigued and have a decreased health-related quality of life and physical functioning in the short-

and long-term. Therefore, interventions that potentially increase health-related quality of life are strongly needed. Exercise training interventions have been shown to effectively improve health-related quality of life in patients with various types of cancer. So far, comparable evidence for patients with esophageal cancer is lacking. We hypothesize that a 12-week supervised combined endurance and resistance training intervention will increas health-related quality of life in patients after esophageal cancer surgery with curative intent.

Study objective

Primary Objective:
- To investigate whether a 12-week exercise intervention increases HRQoL in patients after curatively intended EC surgery compared to a usual care control group.
Secondary Objective(s):
- To investigate whether a 12-week exercise intervention improves fatigue, physical activity, physical fitness, functional wellbeing and symptoms, esophagus-specific QoL, anxiety and depression, diet, sleep quality, body composition, work ability and blood markers.
- To explore whether disease recurrence is lower and overall survival is higher in the exercise group than in the control group.

Study design

Design: A single blind randomised controlled clinical study.

Intervention

The standardized intervention combining endurance and resistance training will take place twice weekly during 12 weeks and will be supervised by a physiotherapist in an out-patient or general physiotherapy practice. The control group will receive care as usual (no exercise program).

Study burden and risks

The patient will be asked three times to spend 45 minutes completing questionnaires about general and mental health, fatigue, work ability, medical history, and exercise habits. Patients will be asked to visit the research center two times for physical examination, blood sampling and to perform several physical tests: cardiopulmonary exercise testing, muscle strength testing and assessment of body composition. Completing questionnaires and physical tests might confront the patient with the consequences of his/her disease which may be experienced as a psychological burden, but on the other hand can also enhance the patients* confidence in his/her ability to be physically active. Patients allocated to the intervention group are supposed to

participate in a 12-week combined endurance and resistance training program twice weekly. To reduce the burden of travelling to the training facilities, the training will take place in an out-patient or general physiotherapy practice near by the patients* home. Injuries due to exercise can occur; to minimize the risk the intensity of the exercise program will be gradually increased during the study and the program will be supervised by a physiotherapist. The estimated extra risk for the patient while participating in this study is low.
Benefit: We expect that the exercise program will have a beneficial effect on the patients* health status. The control group will be offered an exercise advice at the end of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients after EC resection with curative intent, with or without neoadjuvant chemoradiation
- Patients *18 years of age
- Patients with sufficient Dutch writing and reading skills
- Patients who exercise * 150 min/week
- Karnofsky Performance status *60
- Able to walk *60 m

Exclusion criteria

- Presence of metastatic disease
- Contraindication for physical activity on the Revised Physical Activity Readiness Questionnaire (PARQ)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2015
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-01-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-05-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-06-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-07-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-07-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-07-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-09-2015

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-11-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-07-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-11-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-11-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-02-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-05-2018

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-02-2020
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27368
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51091.041.14
OMON	NL-OMON27368

Study results

Date completed:	06-12-2019
Actual enrolment:	120