The effect of exeRcise And Diet on quality of life in patients with Incurable Cancer of Esophagus and Stomach

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

Summary

ID

NL-OMON56382

Source
ToetsingOnline

Brief title
RADICES

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
cancer of the upper GI tract, gastroesophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cancer, diet, exercise, quality of life

Outcome measures

Primary outcome

Quality of life.

Secondary outcome

Physical effects

1. Aerobic capacity

2. Muscle strength

3. Muscle mass and fat mass

4. Weight

5. Nutritional status including sarcopenia

6. Physical activity

7. Toxicity

8. WHO performance status

Patient reported outcomes

1. Physical activity

2. Physical functioning, role functioning and fatigue

Medical effects

1. Percentage of patients starting systemic treatment

2. Dose reductions and delays

3. Duration of systemic therapy

4. Progression free and overall survival

Exploratory endpoints

1. Other Patient Reported Outcomes as measured by the POCOP questionnaire

2. Dietary intake

3. Cost efficacy

Intervention group only:

1. (Serious) Adverse events potentially related to the exercise intervention

2. Satisfaction with the exercise and nutritional intervention (intervention

group only)

3. Adherence and compliance to the exercise and diet intervention

Study description

Background summary

We know that exercise is safe for patients with non-metastatic cancer and that it has a positive effect on the disease and treatment-related side effects. Exercise has been shown to have a positive effect in people treated for non-metastatic esophageal cancer. They are less tired, are fitter and experience a better quality of life. However, we know little about what exercise in combination with nutrition can mean for patients with metastatic oesophageal or gastric cancer. It is possible that exercise in combination with nutrition in these patients also improves their quality of life, but we do not know that at the moment.

Study objective

The aim of the RADICES study is to investigate the effects of a 12-week exercise and nutrition intervention for patients with metastatic oesophageal or gastric cancer. The intervention will be completely tailored to the condition and nutritional status of the patient. We will look at what this combined

intervention does to quality of life and other aspects related to the disease and the treatment of the patients.

Study design

When the patient chooses to participate in the RADICES study, the patient will be randomly assigned to one of two groups:
1. Intervention group
2. Control group

The intervention in this study is a 12-week exercise and nutrition intervention (described below). The effects of this intervention on the quality of life of patients in the intervention group are compared with the control group. All participants, in both groups, will receive usual medical care and treatment.

Intervention

The intervention in this study is a 12-week exercise and nutrition intervention. Exercise intervention: the patient trains for an hour twice a week under the supervision of a physiotherapist in the area. The program consists of strength training (eg squats) and endurance training (eg cycling). During the entire 12-week exercise program, the patient should also exercise without supervision, i.e. at least 30 minutes a day. When moving without guidance, the patient receives help from an exercise meter (Fitbit).

Nutritional intervention: The dietitian will assess the patient's nutritional status and based on this, formulate personal nutrition-related goals together with the patient. The patient receives concrete advice about the composition of your diet, the number of meal times and the aim is to consume a suitable amount of energy and protein for the patient. If necessary, medical nutrition (such as liquid nutrition or tube feeding) is also used for this purpose. After training a bolus protein intake is adviced.

If the patient is assigned to the control group, he will receive an exercise meter (Fitbit), exercise advice that encourages the patient to exercise and information about nutrition as is customary in their own hospital.

For the examination it is necessary that the patient comes to the hospital 2 times in 3 months. A visit takes about 2 to 3 hours. During these visits the following happens:
- We do a physical examination and measure fitness:
o We measure height, weight, heart rate, blood pressure and muscle and fat mass.
o We do a number of standard tests so that we can determine physical fitness
- Complete questionnaires
o We will ask the patient to complete standardized questionnaires at baseline, at 6 weeks, three months and then every three months. During the intervention

period there is also a short list that is administered every two weeks.
o We ask the patient to keep a detailed food diary two times over 3 days

Study burden and risks

We do not expect the intervention to have adverse effects on the participants, except for the necessary time investment, possible muscle or joint injuries and feeling *full* due to the nutritional intervention. Current exercise-oncology guideline state that the risk of adverse events when exercise during treatment is low.(9) The physiotherapist will prevent injuries and adjust the training schedule if necessary and so will the dietician regarding the dietatery measures. Potential benefits for the participants in this study include better QOL, longer duration of anticancer treatment and longer survival.

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

• Incurable adenocarcinoma of the esophagus or stomach.
• Progressive disease after treatment with curative intent OR metastatic disease at primary diagnosis.
• Able and willing to perform the exercise and nutritional program and wear the activity tracker.
• Able and willing to fill out the POCOP/RADICES questionnaires.
• Life expectancy > 12 weeks
• Age >= 18 years.

Exclusion criteria

• Unstable bone metastases inducing skeletal fragility as determined by the treating clinician.
• Untreated symptomatic known brain metastasis.
• Serious active infection.
• Too physically active (i.e. >210 minutes/week of moderate-to-vigorous intentional exercise) or engaging in intense exercise training comparable to the RADICES exercise program.
• Severe neurologic or cardiac impairment according to the American College of Sports Medicine criteria.
• Uncontrolled severe respiratory insufficiency as determined by the treating clinician or if the patient is dependent on oxygen suppletion in rest or during exercise.
• Uncontrolled severe pain.
• Any other contraindications for exercise as determined by the treating physician.
• Any circumstances that would impede adherence to study requirements or ability to give informed consent, as determined by the treating clinician.
• Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2024
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO Date:	27-09-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-08-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06138223
CCMO	NL83835.018.23