MEchanisms of TRaining In Cancer (METRIC).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24982

Source
NTR

Brief title
METRIC

Health condition

Colon cancer
darmkanker

Sponsors and support

Primary sponsor: VU University Medical Center:
LM Buffart
TA Altenburg
H Verheul
E Geleijn
R Huijsmans
TE Buffart

VU University:
CJ de Ruijter

UMC Utrecht:
AM May
Source(s) of monetary or material Support: Zuidasrun

Intervention

Outcome measures

Primary outcome

The main outcome of measures of this pilot study are:

a) Measurements of muscles contractile properties, i.e. muscle force, speed of force development and relaxation, and fatigability.

b) Measures of inflammation (CRP, IL-6, TNF-alpha).

c) Measures of the insulin pathway (insulin, IGF, C-peptide).

Secondary outcome

Secondary outcome measures are perceived fatigue, assessed with the Multidimensional Fatigue Inventory (MFI), and health-related quality of life, assessed with the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire C30 (EORTC QL-C30).

Study description

Background summary

Rationale: Fatigue has been identified as one of the most common and distressing symptoms of patients with cancer affecting quality of life (QoL). Reducing fatigue is therefore a key component in optimising daily functioning and QoL of patients with cancer and survivors. Previous studies showed that exercise may improve muscle mass and strength, reduce fatigue and improve QoL in patients with cancer during and after treatment. To date, little information is available in patients with colon cancer diagnosed with stage III. In addition, no information is available on the mechanisms through which exercise exerts its effect on fatigue. This information is crucial to develop more potent and effective interventions.

Objective: The primary objective is to obtain preliminary data on whether (1) chemotherapy treatment results in (a) deterioration of contractile muscle properties and increased muscle fatigability, (b) increased inflammation, (c) deterioration of the insulin-pathway, and (2) resistance and endurance exercise can prevent these effects.

Study design: Prospective pilot randomized controlled trial.

Study population: Patients after surgery diagnosed with stage III colon cancer who will start

adjuvant systemic chemotherapy.
Intervention (if applicable): Participants will participate in a 12-week resistance and endurance exercise intervention during chemotherapy, including 2 sessions per week under supervision of a physiotherapist. They will be randomly assigned into two groups: group A will start their exercise intervention immediately, e.g. at start of the chemotherapy, and group B will start 12 weeks after they started their chemotherapy. Patients will visit the laboratory on three occasions: at baseline, after 12 and after 24 weeks. During these visits, contractile properties of the muscle and fatigability will be determined, using electro stimulation of the muscles of the upper leg (m. quadriceps), and a blood sample will be drawn to assess function of the immune and endocrine system. Each visit will last approximately 120 minutes.
Main study parameters/endpoints: The main study parameters in this pilot study are contractile muscle properties and muscle fatigability, markers of inflammation (C-reactive protein, Interleukin-6, tumour necrosis factor-alpha (TNF-□), and markers of the insulin-pathway (insulin, insuline-like growth factors, C-peptide).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In clinical practice, it has been shown that CytoFys is feasible for patients with cancer, including colon cancer. At baseline and after 12 and 24 weeks follow up, patients will visit the laboratory (VU University, Faculty of Human Movement Sciences) for approximately 120 minutes. During these sessions, muscle properties and fatigue will be assessed, together with perceived fatigue, quality of life and physical fitness. Both measurements of muscle properties and fatigue have been shown to be feasible in various groups of patients. A blood sample will also be drawn.
The effect of physical exercise on function of the muscular, immune and endocrine systems, perceived fatigue and quality of life in colon cancer patients stage III is still unclear. We expect exercise to have beneficial effects on these outcomes.

Study objective

Primary Objective(s):

1. TTo obtain preliminary data on whether (and to which extend) (neo-) adjuvant chemotherapy for colon or breast cancer results in (a) deterioration of contractile muscle properties and increased muscle fatigability, (b) increased inflammation, (c) deterioration of the insulin pathway (within group differences in group B).
2. TTo obtain preliminary data on whether (and to which extend) resistance and endurance exercise can prevent (neo-) adjuvant chemotherapy-induced deterioration of or improve (a) contractile muscle properties and muscle fatigability, (b) immune system function (i.e. reduced inflammation), (c) endocrine system function (i.e. improved insulin pathway) in patients with colon or breast cancer (differences between group A and B).

Secondary Objective(s):

1. To obtain preliminary data on whether improvement in function of the muscular, immune and endocrine systems are associated with:

a. Reduced perceived fatigue

b. Improved health-related quality of life(HRQoL)

Study design

baseline (T0),

12 weeks later (T1)

24 weeks after baseline (T2).

Intervention

Physical exercise: CytoFys
The CytoFys program is supervised by a physical therapist in an outpatient or general practice setting. In this program, participants are encouraged to be physically active for at least 30 minutes per day at Borg level 12-14. The physical therapist will use the Onco-Move method including “active living” to facilitate the daily activity. Every three weeks the physical therapist will discuss the daily activity with the participants, similar to the consults in the Onco-Move program.
Additionally, patients will attend supervised exercise sessions two times per week. These sessions comprise exercises for warming up and cooling down, exercises to maintain or increase aerobic capacity and exercises to maintain or increase muscle strength. The CytoFys program starts with a baseline assessment before the first cycle of chemotherapy and continues for 12 weeks. At the end of the CytoFys program, patients will receive a leaflet providing encouragement and advice on staying physically active.
In short, endurance exercises are performed for 30 minutes per session (with a minimal duration of 15 minutes per exercise), with an intensity of 60% to 80% of the maximal heart rate as observed in the steep ramp test, or a score of 12 to 14 on the Borg scale of perceived exertion. Resistance exercises of 6 large muscle groups are performed for 20 minutes per session, starting with 2 series of 15 repetitions at 50%1RM per exercise and increasing gradually to 8 repetitions at 70%1RM.
In addition, to the exercise program, cardiorespiratory fitness will be assessed by the physical therapist at baseline, and after 12 weeks using a submaximal exercise test.

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Eligibility criteria

Inclusion criteria

Patients with histological confirmed primary colon cancer after surgery for whom adjuvant treatment is indicated (stage III disease aged ≥ 18 years, and are willing to comply with Cytofys are eligible for this study.

Exclusion criteria

Patients who:

- are not able to perform basic activities of daily living such as walking or biking (i.e., inability to come to the hospital for training twice a week and walk from one location in the hospital to another);

- show cognitive disorders or severe emotional instability (e.g., Schizophrenia, Alzheimer, alcohol addiction);

- are suffering from other disabling co-morbidity that might hamper physical exercise (e.g. heart failure (NYHA classes 3 and 4), chronic obstructive pulmonary disease (COPD, gold 3 and 4), orthopaedic conditions and neurological disorders (e.g., hernia, paresis, amputation, active rheumatoid arthritis);

- are unable to understand and read the Dutch language will be excluded from the study;

- received prior or concurrent anticancer chemotherapy, immunotherapy or investigational drug therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2013
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43997
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3944
NTR-old	NTR4105
CCMO	NL41283.029.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43997

Study results

Summary results
N/A