Optimal Timing of a tailored Physical Activity program during chemotherapeutic Cancer Treatment to reduce long-term cardiovascular morbidity.

Published: 07-01-2013
Last updated: 26-04-2024

To investigate whether a tailored physical activity program that starts early (during curative chemotherapy with cardiovascular toxic potential) is superior in terms of reducing long-term cancer-treatment-related metabolic syndrome and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47553

Source
ToetsingOnline

Brief title
ACT trial

Condition

- Other condition
- Metabolism disorders NEC
- Miscellaneous and site unspecified neoplasms benign

Synonym
cardiovascular effect after chemotherapy

Health condition

cardiovasculaire aandoeningen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chemotherapy, Metabolic syndrome, Physical activity program, Reducing cardiovascular risk factors

Outcome measures

Primary outcome

The primary endpoint is the difference in VO2 max between the groups 1 year

after completion of the PA program.

Secondary outcome

Secondary endpoints will be muscle strength, change in metabolic and

cardiovascular damage parameters, cardiovascular risk factors, cellular

senescence and quality of life including self-efficacy, fatigue, motivation for

exercise and physical activity level.

Study description

Background summary

The number of long-term cancer survivors is growing. As a result, treatment-related morbidity * such as cardiovascular disease, metabolic syndrome, functional decline and fatigue * is impacting quality of life and impairing survival. The development of metabolic syndrome and other cardiovascular risk factors can be observed even during the first years of follow-up of cancer survivors.
Due to high cure rates in recent decades, testicular cancer survivorship is a

paradigm for survivorship-related issues in young adult cancer survivors. Our research group found a 25% prevalence (a striking 2-fold increased risk compared to the age-matched controls) of metabolic syndrome in long-term testicular cancer survivors treated with platinum-based chemotherapy. Moreover, current data have also shown this association between cancer treatment and metabolic syndrome in other cancer survivors. Metabolic syndrome in the general population is currently treated with lifestyle advice to increase physical activity and reduce caloric intake. However, this approach is still underused as standard care for cancer survivors, even though recent meta-analyses have shown the beneficial effects of physical fitness.
Previous studies focused primarily on physical fitness, but did not provide evidence for the best starting point of the physical activity programs and did not focus on sustainable effects or prevention of cardiovascular risk factors clustered in metabolic syndrome. Investigating these aspects with large randomized clinical trials using cardiovascular events as a primary endpoint would delay the implementation of potential lifestyle-changing programs. We have chosen a novel approach and investigate the effects of an early starting point for a tailored PA program for cancer survivors during chemotherapeutic treatment compared with a late starting point (post-treatment).

Study objective

To investigate whether a tailored physical activity program that starts early (during curative chemotherapy with cardiovascular toxic potential) is superior in terms of reducing long-term cancer-treatment-related metabolic syndrome and cardiovascular morbidity to a program that starts late (after completion of chemotherapy).

Study design

A multi center study, to propectively evaluate the application of a tailored physical activity program in patients treated with curative intent with chemotherapy. Patients treated with curative systemic chemotherapeutic treatment for testicular cancer, early colon cancer, early breast cancer or B-cell non-Hodgkin lymphoma (B-NHL) will be randomized at the start of treatment in two groups: early or late. The early group will start the PA program during chemotherapy for 3 months, and after completion of chemotherapy for 3 months (total 6 months). The late group will start the PA program after completion of the chemotherapy for 6 months. In both groups the program will be performed in the UMCG trainings facility, the Martini Hospital Groningen or in a hospital of the Ommelander Ziekenhuis Groep (Delfzicht in Delfzijl, Lucas in Winschoten) for the first 3 months and at home for the next 3 months. During this last 3 months patients will be coached by telephone/email and during regular follow up visits. There will be a stratification for diagnosis.

Intervention

The exercise program will consist of two components: improvement of physical fitness and empowerment to adopt a healthy lifestyle. Improvement of physical fitness will be divided into an aerobic exercise program and a muscle exercise circuit focused on physical performance and muscle strength, respectively, and both will be personalized based on patients* individual exercise capacity. The intensity of aerobic exercise program will be prescribed on the basis of the VO2 max and the 1 Repetition Maximum (1-RM) in line with the ACSM guidelines. The aerobic training, three times per week will consist of aerobic exercises that are performed for 30 minutes per session. Exercises can be performed on bicycle ergometers or treadmills and rowergometers. The training will be based on the training heart rate (THR), which can be computed using the Karvonen formulae: THR=HRrest+40 to 75% (HRmax-HRrest). During weeks 1-6, exercise training will be performed at a THR of HRrest+40 to 60%(HRmax-HRrest) and during weeks 7-24 at a THR of HRrest+60 to 70-75 %(HRmax-HRrest). This aerobic exercise training will include a warm-up before and a cool-down after the training.
General muscle strength training of the trunk and the lower and upper extremities will be performed twice per week during 20-30 minutes in accordance with the recommendations of the ACSM . Before training, the individual 1-RM will be defined. Individual intensity of muscle strength training will start at 50% of the 1-RM during the first week, and will be increased by 5-10% over the ensuing weeks with a frequency of 12 repetitions during three series. The resistance program consists of several exercises targeting the following large muscle groups (exercises): 1) m. longissimus, m. biceps brachii, m. rhomboideus (vertical row), 2) m. quadriceps, m. glutei, m. gastrocnemius (leg press), m. pectoralis major, m. triceps (bench press); 4) m. pectoralis, m. triceps brachii, m. deltoideus, m. trapezius (pul over) 5) m. rectus abdominis (abdominal crunch); 6) m. quadriceps, m. glutei, hamstring muscles (lunge).
In addition to the aerobic and muscle strength training once a week (in the first 12 weeks of the program, when all activities take place in the UMCG training facilities) there will be an additional session (around 1 h per week) to empower patients to adopt a healthy lifestyle. This part of the program is aimed at both increasing physical activity during daily life and at reducing sedentary behavior. In addition to self-monitoring by patients, the physiotherapist will use behavioral practices proven to be effective to keep patients motivated to be active.

Study burden and risks

The risks that are associated with physical activity during cancer treatment are anticipated to be low with the proposed physical activity program. The physical burden for the patients consists of several measurements including physical examination (5 or 6 times), VO2 max (5 or 6 times), muscle strength (5 or 6 times), ECG (5 or 6 times), blood samples (5 or 6 times), assessment of intima-media thickness (3 or 4 times), oral glucose tolerance test (5 or 6 times), 24 hours urine collection (5 or 6 times), skin auto fluorescence (5 or 6 times) and in the testicular patient group a skin- and fat biopsy will be

assessed once. In addition, patients have to fill in four questionnaires at 5 or 6 time points which will take approximately 30 minutes to complete. Patients have to perform a training programme for 12 weeks, 3 times a week, under supervision of a physiotherapist in the hospital and 12 weeks at home.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with testicular, early colon, early breast cancer or B-cell non-Hodgkin lymphoma (B-NHL) with an indication for systemic chemotherapy with a curative intent
- Normal blood count at start of systemic treatment
- Patients need to have an adequate physical health, which is defined by diastolic blood pressure >45 mm Hg or <95 mm Hg; heart frequency in at rest < 100 per minute; body temperature below 38°C; respiration frequency in rest below 20 per minute

- Written informed consent
- Adequate cardiac function with a LVEF above the lower limit of normal

Exclusion criteria

- infections requiring actual antibiotics
- signs of ongoing bleeding or fresh petechiae; unexplained bruises
- critical organ impairment due to their malignancy
- not recovered from earlier surgical intervention
- non adequate control of any symptoms of the malignancy
- inability to travel independently to the rehabilitation centre
- cognitive disorder or emotional instability that might impede the participation in the training program
- recent cardiovascular event

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2013
Enrollment:	275
Type:	Actual

Ethics review

Approved WMO

Date:	07-01-2013
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-04-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-04-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NCT01642680
CCMO	NL41087.042.12