EXIST: Physical exercise to improve fitness and combat fatigue in patients with Multiple Myeloma or (non-) Hodgkin*s lymphoma after high dose chemotherapy and autologous stem cell transplantation.

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(1) To evaluate the effectiveness of an individualized exercise program in comparison to standard care with respect to fatigue, physical fitness and health-related quality of life in patients with hematologic malignancies who have undergone HDC and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lymphomas Hodgkin's disease
Study type	Interventional

Summary

ID

NL-OMON36504

Source
ToetsingOnline

Brief title
EXIST

Condition

- Lymphomas Hodgkin's disease

Synonym
(Non-)Hodgkin□s lymphoma, multiple myeloma

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Fatigue, Physical exercise, Physical fitness, Stem Cell transplantation

Outcome measures

Primary outcome

primary outcome variables are fatigue, cardiorespiratory fitness and muscle

strength.

Secondary outcome

Secondary outcome variables include body composition and bone mineral density,

health-related quality of life, physical activity level, satisfaction with the

intervention, mood disturbances, functioning in daily life and return to work.

Study description

Background summary

The use of high-dose chemotherapy (HDC) and autologous stem cell transplantation (SCT) has improved the outcome of hematologic malignancies such as multiple myeloma and (non-) Hodgkin*s lymphoma. However, the long term side effects of this treatment can have a strong negative impact on quality of life. Patients often complain of severe and persistent fatigue and are compromised in their ability to perform normal physical activities. Physical exercise interventions after SCT can have positive effects on physical fitness, quality of life and fatigue. However, the trials conducted so far were of poor to moderate quality, with methological shortcomings related to trial design, sample size, choice of comparison groups, outcome measures and duration of follow up. There is a need for a rigorous, appropriately controlled assessment of the effectiveness and cost-effectiveness of exercise in these patients.

Study objective

(1) To evaluate the effectiveness of an individualized exercise program in comparison to standard care with respect to fatigue, physical fitness and health-related quality of life in patients with hematologic malignancies who have undergone HDC and autologous SCT. (2) To evaluate the cost-effectiveness of this exercise program.

Study design

Following a small pilot study to evaluate feasibility of the process of training and assessments, a prospective, randomized controlled trial will be performed in 120 patients with multiple myeloma or relapsed (non)Hodgkin*s lymphoma who have undergone induction chemotherapy followed by high-dose chemotherapy and autologous SCT. Patients will be randomized to either the intervention group or the control group. The intervention will start 6-12 weeks after SCT and will consist of an 18-week supervised high-intensity exercise program (2x/wk aerobic and resistance exercise). 3 booster sessions at increasing intervals (4, 10 and 18 weeks after completion of the intervention program) will be held during which patients are trained and counseled and motivated to continue exercising and maintaining an active lifestyle in general. The control group will receive the usual care. Patients will be followed until 12 months after the end of the intervention program or a comparable time after SCT in the control group.

Intervention

The intervention will start 6-12 weeks after SCT and will consist of an 18-week supervised high-intensity exercise program (2x/wk aerobic and resistance exercise). 3 booster sessions at increasing intervals (4, 10 and 18 weeks after completion of the intervention program) will be held during which patients are trained and counseled and motivated to continue exercising and maintaining an active lifestyle in general.

Study burden and risks

Burden
All patients participating in the randomized trial will be asked to visit the Academic Medical Centre at 3 times over the study period of 70 weeks to participate in physical fitness examinations. In addition, at baseline and at 12 months follow-up all patients get a DXA scan.
The duration of the physical fitness examinitation will be approximately 1:10 hours. The duration of the DXA scan lies between 15 and 30 minutes. Furthermore an intake (45 min) will take place at first measurement point. 10 min blood withdrawal. Additionally, at the 3 different time points measurements patients will be asked to wear an accelerometer for 5 consecutive

days and fill out questionnaires. The duration for completing the questionnaires is approximately 1 hour. Patients will receive cost diaries which they will send back once a month, this will take about 15 minutes each month. In total, the time cost for examinations will be 12:15 hours. The intervention group will spend an other 34:05 hours on training, counseling and the satisfaction questionnare.

There are no costs related to the interventions for the patients. All travel expense will be compensate.

Risks
Possible medical risks related to the physical fitness tests are considered minimal and the examinations will be done under supervision of a physician. The DXA-scan is a safe and painless examination. The radiation dose of the DXA-scan is minimal. All participating physical therapists are well experienced in providing exercise therapy in patients with cancer. The exercise program is suited to the patient and the risk are considered minimal.

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

-diagnosed with multiple myeloma in first line or or with HL/NHL in first line or first relapse, who have undergone HDC and autologous SCT 6 to 12 weeks ago or who where recently (< 8 months) treated with HDC and autologous SCT and who have completed radiotherapy or their last cycle of consolidation chemotherapy 2 to 6 weeks ago-Sufficiently recovered from the SCT and having peripheral blood recovery;
-Age between 18 and 65 years;
-Ability to cycle on a bicycle ergometer against a load of at least 25 Watt;
-Ability to walk at least 100 meters independently without crutches/cains or walking frame;
-Written informed consent.

Exclusion criteria

-tandem autologous-allogeneic stem cell transplantation
-Severe cognitive impairment;
-Severe emotional instability;
-Insufficient mastery of the Dutch language;
-Presence of extensive osteolytic lesions with risk of fracture;
-Serious cardiopulmonary and cardiovascular conditions;
-Other disabling comorbidity interfering with the intervention program or influencing outcome parameters (a.o. having a pacemaker , epileptic seizures and poorly regulated diabetes mellitus);
-Severe infections;
-Relapse/progression of disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	125
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
Other	clinicaltrials.gov
CCMO	NL32139.018.10