Physical exercise program as an adjuvant therapy for hematopoietic stem cell transplantation: a pilot study

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

Summary

ID

NL-OMON34271

Source
ToetsingOnline

Brief title
Exercise and stem cell transplantation

Condition

- Leukaemias
- Lymphomas Hodgkin's disease

Synonym
(non) Hodgkin's disease, hematopoietische malignicies, Kahler's diseases, leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: bedrijven en particuliere gift,Novartis

Intervention

Keyword: exercise, hematopoietic stem cell transplantation, improved recovery, physical therapy

Outcome measures

Primary outcome

The primary outcome of this study is self-perceived physical functioning

(subscale of SF-36 questionnaire).

Secondary outcome

Global perceived recovery (7-points Likert-scale), tiredness (CIS-20

questionnaire), Quality of life (SF-36 questionnaire), incidence of oral and

lung infections (patient files), length of hospital stay, V02 max (submaximal

bicycle test), muscle strength of large muscle groups (dynamometer), and

lymphocyte count.

Study description

Background summary

A hematopoietic stem cell transplantation (HSCT) is generally perceived as a highly strenuous and stressful treatment when viewed from both a physical and psychological perspective. Regardless this treatment, patients already perceive feelings of discomfort, insecurity and despair due to the simple fact that they suffer from a life threatening disease. This existing physical and psychological burden may be increased substantially while undergoing a HSCT. The procedure is preceded by intensive chemotherapy and total body irradiation after which the formation of blood cells needs to restart by use of the transplanted cells. In the waiting period preceding the HSCT feelings of insecurity may increase and clinical experience learns that many patients want to contribute actively to increase their chances of a successful and speedy recovery.
Over the last years an increasing number of papers describe the promising role of physical exercise programs as adjuvant therapy for treatments of patients with cancer. In the specific case of HSCT positive effects have been reported

for tiredness, therapy-related complications (oral and lung infections) and even a faster recurrence of immune cells (Wiskemann and Huber 2008). Nevertheless, these findings are still not beyond doubt since many of the published RCTs suffer from methodological shortcomings and small sample sizes (n=20). In some cases weaker study designs were used such as before-after studies without controls (Wiskemann and Huber 2008).
In many of the previous studies (Wiskemann and Huber 2008; Liu et al 2009) physical exercise programs were given during the clinical phase or even thereafter whereas we think that physical exercise training might be especially beneficial in the weeks preceding the HSCT. The disadvantage of only physical exercising in the period after the HSCT is that the physical condition of many patients during that period is frail which limits the possibility of delivering an adequate training stimulus. Furthermore, exercising prior to the HSCT corresponds well with the desire of many patients to contribute actively to their treatment in particular during this waiting period. Our proposed exercise program aims to bring patients in a *top level* physical shape as much as possible until just before the HSCT in order to decrease the decline and to speed up recovery afterwards (Wiskemann and Huber 2008).

Study objective

In preparation of a larger RCT we aim to conduct a pilot study which investigates the feasibility of the described physical exercise program and its effects. Purpose of this study is to develop this exercise program, to test the implementation and conduct of the program within the context of the daily care at the Department of Hematology of RUNMC and to gain insight into the magnitude of its effects. This information will be used to calculate the required sample size of the planned RCT.

Study design

A (non-randomized) controlled clinical trial comparing an intervention group (n=15) which receives the physical exercise program to a control group (n=15) with usual care. Measurements will be taken at baseline (6 weeks prior to transplantation), at 6 weeks (just before transplantation) and at 6 weeks and 3 months after transplantation.

Intervention

The intervention group receives an individually adjusted physical exercise program of one hour duration which will be administered two times per week during the 6 weeks prior to the HSCT. The program will be carried out in a gym which is located at the Department of Physiotherapy at the RUNMC. The program consists of a warming up, cardiovascular training to improve endurance, strengthening exercises of large muscle groups, relaxation exercises, breathing exercises and inspiratory muscle training by use of an inspiratory threshold

loading device (ITLD) (Hulzebos et al, 2006). Both breathing exercises and inspiratory muscle training are intended to reduce pulmonary complications. Cardiovascular training will take 15 minutes per session and involves interval training on stationary bicycles with a work load equivalent to 85-90% of each participant*s maximum heart rate. Strengthening exercises of large muscle groups will be carried out on fitness machines (i.e. leg press, chest press, abdominal crunch, back extension and pull down machine). Three series of exercises will be carried out of 5 to 8 repetitions at 70-90% of a one repetition maximum test (1 RM; the maximum amount of weight one can lift in a single repetition for a given exercise). By using a lighter test load and a small number of repetitions the 1 RM can be calculated based on existing tables in textbooks for exercise physiology. To ensure progression, patients will perform a 1 RM test for each exercise every one and a half week. In addition, relaxation exercises consist of progressive muscle relaxation. The physical exercise program will be supervised by a physical therapist who stays in close contact with a nurse and the treating haematologist by means of a regular weekly meeting. In the clinical phase after the HSCT patients also receive a physical exercise program twice a week (as far as possible) during their hospital stay. This program is already part of current usual care. The control group receives usual care which means that they have no additional physical exercise intervention in the 6 weeks prior to the HSCT.

Study burden and risks

There is a chance that patients may feel uncomfortable or unwell while exercising. This could take place during the physical exercise program but also during the measurements (VO2max and Muscle strengths tests). Although physical exercise programs have often been studied in patients with cancer and also in HSCT patients we are not aware of any reports in the literature of unwanted side effects. Further, while exercising patients stay under constant supervision of a physical therapist and if they feel uncomfortable or unwell the exercise will be stopped immediately. Contra-indications will be checked by the Physical Activities Readiness Questionnaire and also after consultation of the treating haematologist.

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 acute or chronic leukemia, Hodgkin*s Lymphoma, non-Hodgkins*s Lymphoma or Multiple Myeloma;
- Scheduled to undergo an allogenic or autologous HSCT;
- No cardiovascular contra-indication to engage in physical activity programs as checked by the Physical Activities Readiness Questionnaire (PAR-Q) (Thomas et al 1992), and/or no other physical limitations for physical exercise programs;
- Sufficient knowledge of the Dutch language;
- Approval to participate in the study by the treating physician, and
- Being aged in the age range 18 years through 65 years

Exclusion criteria

Cardiovascular or other contra-indications (e.g. rheumatic disease) for participating in a physical exercise program. Decisions to exclude potential participants will be made based on the results of the Physical Activities Readiness Questionnaire (PAR-Q) and after consultation with the physician.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	24-12-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL34623.091.10