ISRCTN30955874 https://doi.org/10.1186/ISRCTN30955874

Physical exercise prior to hematopoietic stem cell transplantation

Submission date	Recruitment status	[ ] Prospectively registered
21/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/08/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/08/2013	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A hematopoetic stem cell transplantation is an effective treatment but when viewed from the patients perspective physically and psychologically highly demanding. Attending a physical exercise program in addition might improve recovery in patients undergoing this treatment. This study aims to develop a physical exercise program supervised by a physical therapist to be given before the stem cell transplantation.

Who can participate?
Adult patients with leukaemia, scheduled to undergo a stem cell transplantation who can do physical activity, can participate in the study.

What does the study involve?
Patients will be divided into two groups: the intervention group (patients who live in Nijmegen or the Nijmegen region), who receive a physical exercise program prior to the stem cell transplantation, and the control group (patients who live further away from the Radboud University Medical Centre), who do not receive the physical exercise program. This is an individually adjusted physical exercise program of one hour duration which will be given two times per week during six weeks prior to the stem cell transplantation. It is supervised by a physiotherapist and takes place at the hospital. The program consists of aerobic exercises to improve tolerance, muscle strengthening exercises, muscle training and relaxation exercises.

What are the possible benefits and risks of participating?
Participants allocated to the physical exercise group may gain better and faster recovery following the stem cell transplantation. Adverse events will be followed until they have subsided, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.

Where is the study run from?
The study is carried out at the Radboud University Medical Centre in Nijmegen, the Netherlands.

When is study starting and how long is it expected to run for?
The study started in March 2011 and lasted through February 2012.

Who is funding the study?
The study is funded by a private fund and Novartis.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Physical exercise prior to hematopoietic stem cell transplantation: a feasibility study

Study objectives
A physical exercise program supervised by a physiotherapist and administered in the period shortly before a hematopoietic stem cell transplantation is feasible and safe, and results in improved recovery afterwards.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study is conducted in accordance with the Medical Research Involving Human Subjects Act (WMO). The study protocol is a approved by the Medical Ethical Committee , region Arnhem and Nijmegen, the Netherlands (Reg. No. 2010/404). The date of approval is December 24, 2010.

Study design

Non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients diagnosed with acute or chronic leukemia, Hodgkins Lymphoma, non-Hodgkinss Lymphoma or Multiple Myeloma, and scheduled to undergo an allogenic or autologous HSCT

Interventions
The participants were allocated to the groups based on the postal code of their home address. Participants living in the proximity if the University Medical Centre were allocated to the intervention group and other participants were allocated to the control group.

The intervention is an individually adjusted physical exercise program of one hour duration which will be given two times per week during 4-6 weeks prior to the hematopoietic stem cell transplantation (HSCT). The intervention will be supervised by a physiotherapist and takes place at the hospital. The program consists of aerobic exercises to improve endurance, muscle strengthening exercises, inspiratory muscle training and relaxation exercises.

The control group receives no intervention.

Variables are measured at baseline (T0; 6 weeks prior to HSCT), 6 weeks (T1; before HSCT) and at 6 weeks (T2) and 3 months after HSCT (T3).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. For the primary outcomes self-perceived physical functioning and QOL, patients fill out the Short Form Health Survey (SF-36). With the SF-36, 36 questions are answered to score perceived health related to quality of life (QOL). With this questionnaire 36 questions are grouped into eight domains of which our primary outcome self-perceived physical functioning is one domain. All scores in the SF-36 range from 0-100 points (higher scores are related to better outcome). For QOL, a physical component score (PCS) and a mental component score (MCS) can be derived from the total SF-36 score.
2. With the Checklist Individual Strength (CIS) the primary score for severity in fatigue was evaluated. The questionnaire consists of four domains, of which Severity of Fatigue is one domain. The total CIS score (ranging from 20-140 points) and the score of Severity of Fatigue (ranging from 8-56 points) are evaluated in this study.

Key secondary outcome(s))
1. Physical fitness
The maximum oxygen uptake (peak VO2) is estimated by means of the Åstrandtest. The Åstrandtest is a submaximal 6-minute bicycle test for the aerobic endurance capacity. During the

test the cadence has to be 50 to 60 rpm with a Wattage of 75, 100, 125 or 150. The Wattage is estimated by the researcher based on habitual physical activity and fitness level of the participant and can be increased or decreased during the first 2 minutes of the test. After 2 minutes cycling at 60 rpm the participants heart rate should rise to 130 160 bpm and reach a steady state. The heart rates of minute 5 and 6 of the test will be recorded. With the average heart rate of minute 5 and 6, gender, weight and wattage the VO2 max can be estimated.
2. Global perceived recovery
The global perceived recovery score is used to measure the patients opinion about the effect of the intervention on a 7-point Likert scale ranging from very much deterioration to very much improvement
3. Muscle Strength
The muscle strength of the large muscle groups is monitored with the handgrip dynamometer (JAMAR) and the MicroFET2 (Biometrics Europe BV, Almere, Netherlands). For the handgrip both hands separately apply as much grip pressure as possible on the dynamometer. The MicroFET hand-held dynamometer is used to measure muscle strength of the arm flexors and leg extensors bilaterally on all subjects conform manual. The break test is used which means that the subject is asked to exert a maximum force against the applicator, and the rater rapidly applies a countering force to overcome the subjects exertion. All measurements are performed bilaterally three times and the highest score is used in the analysis.
4. Infections
The amount of leukocytes and trombocytes. Leukocytes and thrombocytes counts are routinely and regularly sampled during the outpatient visit or in the clinic and registered in patient files.
5. Length of stay
Total length of hospital stay was registered by means of the electronic registry system of the hospital.

Baseline (T0; 6 weeks prior to HSCT): SF-36, Checklist Individual Strength (CIS), peak VO2, Muscle strength (handgrip dynamometer and MicroFET2)

6 weeks after baseline (T1; before HSCT): SF-36, Checklist Individual Strength (CIS), peak VO2, Muscle strength (handgrip dynamometer and MicroFET2)

6 weeks after HSCT (T2): SF-36, Checklist Individual Strength (CIS), Global Perceived Recovery Questionnaire (GPE), peak VO2, Muscle strength (handgrip dynamometer and MicroFET2)

3 months after HSCT (T3): SF-36, Checklist Individual Strength (CIS), Global Perceived Recovery Questionnaire (GPE), peak VO2, Muscle strength (handgrip dynamometer and MicroFET2), adherence and satisfaction with treatment (Questionnaire containing statements about the amount and clarity of information, the content of training sessions and measurements evaluated with Likert scales).

Thrombocytes and neutrophiles counts were routinely and regularly sampled during visit to the clinic.

Completion date
01/03/2012

Eligibility

Key inclusion criteria

In order to be selected they need to meet the following inclusion criteria:
1. Diagnosed with acute or chronic leukemia, Hodgkins Lymphoma, non-Hodgkinss Lymphoma or Multiple Myeloma
2. Scheduled to undergo an allogenic or autologous HSCT
3. Sufficient knowledge of the Dutch language
4. Approval to participate in the study by the treating physician, and
5. Being aged in the age range 18 years through 65 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. 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 Activity Readiness Questionnaire (PAR-Q) and after consultation with the physician.

Date of first enrolment
01/03/2011

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
114 IQ healthcare
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Sponsor information

Organisation
Scientific Institute for Quality of Healthcare (Netherlands)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Industry

Funder Name
Novartis

Alternative Name(s)
Novartis AG, Novartis International AG

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Private fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration