ISRCTN61498391 https://doi.org/10.1186/ISRCTN61498391

Effects of evidence-based exercise on body composition, physical fitness, and recovery-related parameters in Hematopoietic Stem Cell Transplantation Patients

Submission date
24/03/2017

Recruitment status
No longer recruiting

Registration date
03/04/2017

Overall study status
Completed

Last Edited
21/09/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hematologic cancers are cancers of the blood. Hematopoietic stem cell transplantation (HSCT) is the primary treatment for hematologic cancers which involves replacing the patient's own immune cells with donated healthy stem cells taken from the bone marrow or blood. Patients who undergo HSCT are at risk of suffering from treatment-related problems. Patients are required to be isolated in a bioclean room (a room without any bacteria), and this can cause patients to be limited in their mobility in these small rooms. This can result in the loss of physical function, fatigue, psychological problems, and decrease of quality of life (QOL). These problems lead to delays in recovery, which can cause delays in being discharged from hospital. Exercise is known to improve physical function, fatigue, depression, QOL, and immune function. The aim of this study is to examine the effect of evidence-based exercise on the body composition and physical fitness, and recovery in HSCT patients.

Who can participate?
Adults aged 18 and older who have blood cancers who are receiving HSCT.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a non-supervised daily exercise plan during their hospital stay. The programme is developed for participants so that they can do it in their hospital room. It includes bed stretching and strengthening exercises. Those in the second group receive their usual care. Participants are assessed for their body composition, physical fitness levels.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in muscle mass and physical fitness. There are no notable risks with participating.

Where is the study run from?
Yonsei Severance Hospital (South Korea)

When is the study starting and how long is it expected to run for?
February 2017 to September 2017

Who is funding the study?
Yonsei Severance Hospital (South Korea)

Who is the main contact?
1. Dr June Won Cheong (Scientific)
2. Professor Justin Jeon (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr June Won Cheong

Contact details
50 Yonsei-ro
Seodaemun-gu
Severance Hospital
Seoul
Korea, South
120-752

Type(s)
Scientific

Contact name
Prof Justin Jeon

Contact details
50 Yonsei-ro
Seodaemun-gu
Yonsei University
Seoul
Korea, South
120-749

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of evidence-based exercise on body composition, physical fitness, and recovery-related parameters in Hematopoietic Stem Cell Transplantation Patients: A randomized controlled trial

Study objectives
Evidence-based exercise will improve muscle mass, physical fitness, and recovery-related parameters in Hematopoietic stem cell transplantation patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Review Board at Yonsei University College of Medicine, 16/03/2017, ref: 4-2017-0058

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Hematopoietic Stem Cell Transplantation Patients

Interventions
Participants are randomly allocated to either the exercise group or to the control group. Randomisation is done using stratified randomisation according to gender and transplanting.

Exercise group: Participants in this group conduct a non-supervised exercise intervention programme at least one time per day during hospitalization in addition to their usual care. The exercise program is divided into three types according to patients' daily condition. The exercise program is divided into two types according to hospital room type. The exercise program includes bed stretching, resistance exercise, and joint strengthening exercise. Participants in

exercise group are educated exercise program by exercise instructor at admission and record daily exercise log book during hospitalization.

Control group: Participants in control group will receive only usual care including chemotherapy, medication, blood count monitoring, and managing side effects like general patients.

Participants are assessed for their body composition and physical fitness using various tests at baseline, after entering the bio-clean room and when they are discharged from the hospital.

Intervention Type
Other

Primary outcome measure
1. Body composition (muscle mass) is measured using the BIA machine (Inbody IH-U070R, Biospace, Korea) at baseline and after entering a bio-clean room, and discharge from hospital
2. Physical fitness is measured using the six min-walking test (or 2 minute walking), step test, hand-grip strength, sit and reach, 8 foot up and go test, and chair stand at baseline and after entering a bio-clean room, and discharge from hospital

Secondary outcome measures
Current secondary outcome measures as of 08/04/2019:
1. Time to platelet engraftment is measured using hospital charts daily during hospital stay
2. Absolute neutrophil count is measured using hospital charts daily during hospital stay
3. Amount of blood transfusion is measured using hospital charts daily during hospital stay
4. Length of hospital stay is measured using hospital charts daily during hospital stay
5. Symptoms are measured using the Korean version of the M. D. Anderson symptom inventory (MDASI) at baseline and after entering a bio-clean room, and discharge from hospital

Previous secondary outcome measures:
1. Time to platelet engraftment is measured using hospital charts daily during hospital stay
2. Absolute neutrophil count is measured using hospital charts daily during hospital stay
3. Amount of blood transfusion is measured using hospital charts daily during hospital stay
4. Amount of meal intake is measured using hospital charts daily during hospital stay
5. Length of hospital stay is measured using hospital charts daily during hospital stay
6. Symptoms are measured using the Korean version of the M. D. Anderson symptom inventory (MDASI) at baseline and after entering a bio-clean room, and discharge from hospital
7. Satisfaction in exercise program is measured using Satisfaction with Life Scale (SLS) at discharge from hospital

Overall study start date
15/02/2017

Completion date
15/09/2017

Eligibility

Key inclusion criteria
1. Patients with leukemia, lymphoma, or multiple myeloma who are scheduled to receive autologousor allogeneic HSCT
2. Aged between 18 and 65 years

3. Ability to understand and provide written informed consent in Korea
4. No evidence of cardiac or pulmonary failure associated with treatment
5. Ability to conduct low and moderate intensity exercise program

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 patients in each group

Key exclusion criteria
1. Existing evidence of recurrent or metastatic disease
2. Pregnant or planned to be pregnant within six month
3. Any condition unsuitable for participation in the study

Date of first enrolment
16/03/2017

Date of final enrolment
15/08/2017

Locations

Countries of recruitment
Korea, South

Study participating centre
Yonsei Severance Hospital
50 Yonsei-ro
Seodaemun-gu
Seoul
Korea, South
120-752

Sponsor information

Organisation
Yonsei Severance Hospital

Sponsor details
50 Yonsei-ro
Seodaemun-gu
Seoul
Korea, South
120-752

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/044kjp413

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Yonsei University

Alternative Name(s)
YONSEI University, Seoul, Korea, Yonsei University in South Korea

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
15/09/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		03/04/2019	08/04/2019	No	No
Results article	qualitative study results	16/09/2020	21/09/2020	Yes	No