Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The Effect of Aerobic Exercise on Promoting Hematopoietic Stem Cells Engraftment in Patients Undergoing Autologous Hematopoietic Cell Transplantation

Protocol summary

Study aim

The Purpose of This Study Is To Determine The Effect of the effect of One Week Regular Aerobic Training on The Production of CD34+ Hematopoietic Cells And To Promote The Homing Process of Hematopoietic Stem Cells From The Blood To The Bone Marrow, And in other words, To Determine The Bone Marrow Regeneration Capacity In Hematopoiesis After Autologous Hematopoietic Cell Transplantation.

Design

Patients with lymphoma and multiple myeloma leukemia were divided into one of two intervention groups (aerobic exercise program and routine treatment program) or control (routine treatment program without exercise) based on a random list.

Settings and conduct

This project is carried out on blood cancer patients who are candidates for autologous bone marrow transplantation and at the blood stem cell transplant center of Taleghani Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Included Criteria: Autologous Peripheral Blood Stem Cell Transplantation, Age Between 22 And 62 Years, Performing An Exercise Test Under The Supervision Of a Cardiologist, Karnofsky Performance (KPS) With Scores Above 90, Siutable Functional Capacity Of The Patients For Walking On The Treadmill, The Absence Of Concomitant Chronic Diseases Such as Diabetes And Respiratory Disease. Excluded Criteria: Hemoglobin Below Eight Micrograms Per Liter, Reduction of Platelets Below 50,000, Symptoms Of Fever, Neutropenia, Bleeding, Nausea.

Intervention groups

Intervention group: Mobilization is done through the injection of granulocyte colony stimulating factor and a week of treadmill training with an intensity between 40 and 60% of the reserve heart rate for 20-30 minutes.

Control group: mobilization through routine injection of granulocyte colony stimulating factor alone and without receiving exercise intervention.

Main outcome variables

Counting white blood cells, hemoglobin, platelets and CD34+ cells

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220708055415N1**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Masoomeh Kamyabnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4401 8556

Email address

m_kamiyab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aerobic Exercise on Promoting Hematopoietic Stem Cells Engraftment in Patients Undergoing Autologous Hematopoietic Cell Transplantation

Public title

Investigating The Effect of Aerobic Exercise on Hematopoietic Stem Cells Engraftment in Patients Undergoing Autologous Hematopoietic Cell Transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Malignant Disease with Indication of HSCT, Transplantation of Peripheral Blood Stem Cells by Autologous Method, Age between 22 and 62 Years, Performing an Exercise Test Under the Supervision of a Cardiologist to Check the Patient's Cardiovascular Condition. Karnofsky Performance (KPS) with Scores Above 90 Suitable Functional Capacity of the Patient for Walking on the Treadmill. No History of Chronic Diseases such as High Blood Pressure, Severe Heart Failure, Respiratory Disease and Allergies, Diabetes, Kidney Failure, and Orthopedic Problems No History of Treatment and Radiotherapy

Exclusion criteria:

Hemoglobin Below Eight Micrograms Per Liter Decrease in Platelets Below 50,000 Symptoms of Fever, Neutropenia, Bleeding, Nausea

Age

From **22 years** old to **62 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This Study Is a Simple Randomization Type, Individually, Using a Table of Random Numbers, And the Sequence Is Obtained by Referring to Randomization.Com.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, Apart From The Patients Themselves And The Main Researcher And The Relevant Treating Doctors, All The Treatment Staff, Including Other Doctors, Nurses, The Person Responsible For Data Collection And Analysis, Are Blind To The Intervention Group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Bone Marrow Transplant Center ,Taleghani Hospital, Shahid Arabi Stree, Yaman St, Shahid Chamran highway

City

Tehran

Province

Tehran

Postal code

198571151

Approval date

2023-01-22, 1401/11/02

Ethics committee reference number

IR.SBMU.REC.1401.030

Health conditions studied

1

Description of health condition studied

Multiple myeloma

ICD-10 code

C90.0

ICD-10 code description

Multiple myeloma

2

Description of health condition studied

non-Hodgkin lymphoma

ICD-10 code

C85

ICD-10 code description

Other specified and unspecified types of non-Hodgkin lymphoma

Primary outcomes

1

Description
White blood cell count
Timepoint
Before and after transplantation
Method of measurement
Analyzer device, model Hitachi 912 made by Roche, Germany

2

Description
Hemoglobin count
Timepoint
Before and after transplantation
Method of measurement
Analyzer device, model Hitachi 912 made by Roche, Germany

3

Description
Platelet count
Timepoint
Before and after transplantation
Method of measurement
Analyzer device, model Hitachi 912 made by Roche, Germany

Secondary outcomes

1

Description
The number of platelet units injected
Timepoint
After transplantation
Method of measurement
Counting the number of platelet units injected

2

Description
CD34+ hematopoietic progenitor cells
Timepoint
Before and after transplantation
Method of measurement
flow cytometry (Attune NXT, USA Country)

Intervention groups

1

Description
Intervention group: After hospitalization and before transplantation, the patients are first subjected to the mobilization and release of stem cells for about 7 days through the injection of granulocyte colony stimulating factor (GCSF) at the rate of 5-10 (µg/kg per day). In order to implement the sports intervention, informed and written consent is received from the patients. Exercise protocol: First, the patients of the intervention group get to know how to work with the treadmill and the exercise program. On the first day, before starting work on the treadmill and performing the pre-test, the resting heart rate of each patient is recorded by an experienced examiner after at least 5 minutes of rest (sitting or lying down). Because the heart rate response is easily altered by a number of environmental (eg, heat, humidity), dietary (eg, caffeine, after the last meal), and behavioral (eg, anxiety, smoking) factors, patients at least They refrain from smoking or consuming caffeine 30 minutes before the measurement. In each session, before exercising on the treadmill, a 5-minute warm-up with stretching and aerobic exercises is done. Each patient exercises on a treadmill with a zero slope, with an initial intensity of about 40% of the reserve heart rate (HR Reserve) [resting heart rate - maximum heart rate (age - 220) = reserve heart rate], a speed of 0.8 km/h and He starts the 12-minute period that is set, and every day, 5% is added to the training intensity (increasing the training speed by 0.25 km/h) and 3 minutes to the training time, until on the seventh day, approximately The training intensity increases to 60% of the reserve heart rate, the training speed to 2.3 km and the training time to 30 minutes. In the 5 minutes at the end of the training program of each session, the speed gradually decreases and then stops completely. The increase in speed is due to the ability of the patient, who pays full attention to the patient, and the heart rate is continuously monitored during the test, and his condition is monitored and recorded by the examiner (exercise physiologist) at each stage. After performing aerobic exercise on the first day of mobilization and after 7 consecutive days, which is the end of the mobilization period, a blood sample of 5 cc was taken from each patient, immediately after exercise in order to evaluate the number of CD34+ cells, as well as blood samples during hospitalization. And at the time of discharge, in order to measure the amount of white blood cells, hemoglobin and platelets, they are taken from the patients of both groups by a technician and immediately transferred to the transplant laboratory.
Category
Treatment - Other

2

Description
Control group: Control group: mobilization and release of stem cells through routine injection of granulocyte colony stimulating factor (GCSF) alone and without exercise intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person

Masoomeh Kamyabnia

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Hospital postal code. 1985711151, Shahid Arabi St, Yaman St, Shahid Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Abbas Haji Fathali

Street address
Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yaman Street, Shahid Chamran Highway

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taleghanihospital@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
50

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Masoomeh Kamyabnia

Position
University Faculty

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All the Results of This Study Will Be Published in Several Articles in a Reputable Journals.
When the data will become available and for how long
1401-1402
To whom data/document is available
All people
Under which criteria data/document could be used
In any situation and for any purpose
From where data/document is obtainable
Masoomeh Kamyabnia m_kamiyab@yahoo.com
What processes are involved for a request to access data/document
As soon as the request is received
Comments