Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of aerobic and resistance exercise therapy on the cell count of hematopoetic cancerous patients for autologous bone marrow transplantation

Protocol summary

Study aim
Evaluation of the effect of aerobic and resistance exercises on cell count of bone marrow transplant patients

Design
hematopoetic cancerous patients (multiple myeloma and Hodgkin's lymphoma) who are undergoing autologous bone marrow transplantatio will be randomization to one of Intervention (standard pre-transplant treatment + exercise) and control groups (standard pre-transplant treatment-without exercise)

Settings and conduct
This is a joint study between the sports medicine and bone marrow transplantation departments of Taleghani Hospital, Tehran, Iran on hematopoetic cancerous patients who will need autologous bone marrow transplantation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age: 16-65 years old multiple myeloma or Hodgkin disease confirmed by pathology treatment option : autologous bone marrow transplantation willing to participation Exclusion criteria: concomitant chronic disease (Hypertension, Diabetes, Chronic Kidney disease) concomitant orthopedic deficiency interrupting exercise not willing to do 14 aerobic exercise session in 4 weeks not willing to do 8 resistance exercise session in 4 weeks history of hemoglobin level less than 8 g/dl history of platelet less than 50000/microl History of fever and neutropenia

Intervention groups
Intervention group: aerobic exercise with 40% max intensity, 6 day/week and resistance exercise every other day for 4 weeks + standard pre-transplant treatment Control group: standard pre-transplant treatment (without exercise)

Main outcome variables
Hospital admission days after transplant; Bone marrow sample WBC count; Bone marrow sample mono nuclear CD34+ cell count;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170921036304N2**
Registration date: **2018-06-05, 1397/03/15**
Registration timing: **retrospective**

Last update: **2018-06-05, 1397/03/15**
Update count: **0**

Registration date
2018-06-05, 1397/03/15

Registrant information

Name
Bahar Hassanmirzaei

Name of organization / entity
Iran Football Medical Assessment and Rehabilitation Center

Country
Iran (Islamic Republic of)

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+98 21 4473 8641

Email address
bahariane@ifmarc.ir

Recruitment status
Recruitment complete

Funding source
Shahid Behehsti University of Medical Sciences

Expected recruitment start date
2017-01-01, 1395/10/12

Expected recruitment end date
2017-09-02, 1396/06/11

Actual recruitment start date
2017-01-01, 1395/10/12
Actual recruitment end date
2017-09-02, 1396/06/11
Trial completion date
empty

Scientific title
Study of the effect of aerobic and resistance exercise therapy on the cell count of hematopoetic cancerous patients for autologous bone marrow transplantation

Public title
exercise therapy to improve cell count in autologous bone marrow transplantation in hematopoetic cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age :16-65 years old multiple myeloma or Hodgkin disease confirmed by pathology treatment option : autologous bone marrow transplantation willing to participation
Exclusion criteria:
no concomitant chronic disease (Hypertension, Diabetes, Chronic Kidney disease) concomitant orthopedic deficiency interrupting exercise not willing to do 14 aerobic exercise session in 4 weeks not willing to do 8 resistance exercise session in 4 weeks history of hemoglobin level less than 8 g/dl history of platelet less than 50000/microl History of fever and neutropenia
Age
From **16 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**
Actual sample size reached: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization of this study is individual simple randomization, by using the table of randomized number and the sequence will be made online by www.randomization.com.
Blinding (investigator's opinion)
Double blinded
Blinding description
As the patients and main researcher who is responsible for describing and allocating the patients into groups , all other medical staff consisting of the assessment team , the treatment team and those who are responsible for collecting and analyzing data, are blind.
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
Arabi Ave, Daneshjoo Blvd, Velenjak
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Postal code
1985717443
Approval date
2017-01-01, 1395/10/12
Ethics committee reference number
IR.SBMU.MSP.REC.1395388

Health conditions studied

1

Description of health condition studied
Hematopoetic cancer
ICD-10 code
C96.Z
ICD-10 code description
Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue

Primary outcomes

1

Description
Bone marrow sample WBC count for transplant
Timepoint
after 4 weeks of standard pre-transplant treatment (control group) or 4 weeks exercise in addition to standard pre-transplant treatment (intervention group)
Method of measurement
the number of mononuclear and CD34 cells by the report of pathologist

Secondary outcomes

1

Description
Hospital admission length after transplant

Timepoint
after patients discharge
Method of measurement
admition days based on the hospital documentation

Intervention groups

1

Description
Intervention group: aerobic and resistance exercise for 4 weeks in addition to standard pre-transplant treatment
Category
Treatment - Other

2

Description
Control group: standard pre-transplant treatment without receiving exercise prescription
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
بهار حسن میرزایی
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Arabi Ave, Daneshjoo Blvd, Velenjak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
100
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
Shahid Beheshti University of Medical Sciences
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Dr. Bahar Hassanmirzaei
Position
Resident
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Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is 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 data and results will be published as an article in a scientific journal.
When the data will become available and for how long
2018
To whom data/document is available
verybody
Under which criteria data/document could be used
In all situations, for every body
From where data/document is obtainable
Dr. Bahar Hassanmirzaei bahariane@yahoo.com
What processes are involved for a request to access data/document
Upon the request is recieved
Comments