

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Study of the effect of aerobic and resistance exercise therapy on the cell count of hematopoietic 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

hematopoietic cancerous patients (multiple myeloma and Hodgkin's lymphoma) who are undergoing autologous bone marrow transplantation will be randomized 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 hematopoietic 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)

##### Phone

+98 21 4473 8641

##### Email address

baharlane@ifmarc.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Shahid Beheshti 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 hematopoietic cancerous patients for autologous bone marrow transplantation

**Public title**

exercise therapy to improve cell count in autologous bone marrow transplantation in hematopoietic 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](http://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

**City**

Tehran

**Province**

Tehran

**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**

Hematopoietic 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**

admission 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

**Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2303 1406

**Email**

bahariane@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Rezghi

**Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2303 1406

**Email**

bahariane@yahoo.com

**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

**Full name of responsible person**

Dr. Bahar Hassanmirzaei

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

**Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2387 1000

**Fax****Email**

bahariane@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Shahrzad Khosravi

**Position**

Sports and Exercise Medicine Specialist

**Latest degree**

Specialist  
**Other areas of specialty/work**  
Sport Medicine  
**Street address**  
Arabi Ave, Daneshjoo Blvd, Velenjak  
**City**  
Teharn  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 2387 1000  
**Fax**  
**Email**  
info@sbmu.ac.ir  
**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr. Bahar Hassanmirzaei  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Sport Medicine  
**Street address**  
Arabi Ave, Daneshjoo Blvd, Velenjak  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443

**Phone**  
+98 21 2303 1406  
**Fax**  
**Email**  
bahariane@yahoo.com  
**Web page address**

## 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