Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The efficacy of pentoxifylline in suppressing the regulatory T (Tregs) cells in multiple myeloma (MM) patients undergoing autologous hematopoietic stem cell transplantation (ASCT) compared to the control group and its impact on disease outcome

Protocol summary

Study aim
The efficacy of pentoxifylline in suppressing the regulatory T (Tregs) cells in multiple myeloma patients undergoing autologous hematopoietic stem cell transplantation (ASCT) and its impact on disease outcome

Design
This study is a Phase II clinical trial with the control group that will be randomized by the sequentially numbered, opaque, sealed envelope (SNOSE) method. The participants have been randomly divided into two groups of 15 people, pentoxifylline and control.

Settings and conduct
Eligible patients will be selected from those referred to the BMT department of Taleghani Hospital for ASCT.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with symptomatic MM Patients must be in complete response after primary therapy. MM patient must be a candidate for ASCT Age greater than or equal to 21 and less than or equal to 70 years old. HIV Negative and no active Hepatitis B or C. Exclusion Criteria: Patients with CNS Myeloma at time of enrollment. Patients with cardiac, pulmonary, hepatic diseases. Active autoimmune disease including but not limited to: Rheumatoid arthritis, Inflammatory bowel disease, Celiac disease, Systemic lupus erythematosis, Scleroderma or Multiple sclerosis. Use of systemic immunosuppressive medications, including tacrolimus, mycophenolate mofetil, sirolimus or cyclosporine A. Psychiatric illness which may make compliance to the clinical protocol unmanageable or which may compromise the ability of the patient to give informed consent.

Intervention groups
Group 1: 15 patients with multiple myeloma undergoing ASCT who receive only routine treatment. Group 2: 15 patients with multiple myeloma undergoing ASCT who receive routine treatment and pentoxifylline.

Main outcome variables
T regulatory cells (Tregs) and T CD8+ IL-10, TGF-B and IFN-G

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230315057722N1**
Registration date: **2023-06-14, 1402/03/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-14, 1402/03/24**
Update count: **0**

Registration date
2023-06-14, 1402/03/24

Registrant information

Name
Samareh Younesian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-15, 1402/02/25

Expected recruitment end date
2024-11-16, 1403/08/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy of pentoxifylline in suppressing the regulatory T (Tregs) cells in multiple myeloma (MM) patients undergoing autologous hematopoietic stem cell transplantation (ASCT) compared to the control group and its impact on disease outcome

Public title
Effect of pentoxifylline in multiple myeloma (MM) patients undergoing autologous hematopoietic stem cell transplantation (ASCT)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with symptomatic MM Patients must be in complete response (CR) after primary therapy. MM patient must be a candidate for autologous hematopoietic stem cell transplantation (ASCT) as determined by treating physician. Age greater than or equal to 21 and less than or equal to 70 years old. HIV Negative and no active Hepatitis B or C.
Exclusion criteria:
Patients with CNS Myeloma at time of enrollment. Patients with cardiac, pulmonary, hepatic diseases. Active autoimmune disease including but not limited to: Rheumatoid arthritis, Inflammatory bowel disease, Celiac disease, Systemic lupus erythematosis, Scleroderma or Multiple sclerosis. Use of systemic immunosuppressive medications, including tacrolimus, mycophenolate mofetil, sirolimus or cyclosporine A. Psychiatric illness which may make compliance to the clinical protocol unmanageable or which may compromise the ability of the patient to give informed consent.
Age
From **21 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Peripheral blood samples will be taken from the participants (PTXF and control groups) on day +14 and day +99.
Randomization (investigator's opinion)
Randomized
Randomization description
1. Random sequence generation: Patients were assigned in groups according to the random allocation rule. Based on the size of the research sample, we prepared 30 cards on which the PTXF and control groups were recorded and placed these cards in a lottery container. Then the cards are randomly removed from the container without replacement, and the created sequence is recorded. 2. Allocation concealment: The sequentially numbered, opaque, sealed envelope (SNOSE) method is used to perform randomization. Based on the sample size of the research, several envelopes were prepared with aluminum wrappers, and each of the random sequences created on a card was recorded and the cards were placed in the envelopes of the letter, respectively. To maintain a random sequence, the envelopes were numbered in the same way on the outer surface. Finally, the lids of the letter envelopes were glued and placed in a box, respectively. 3. Randomization execution: At the beginning of the registration of the participants, according to the order of entry of the eligible participants, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Not blinded
Blinding description
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
Shahid Beheshti University of Medical Sciences, School of Allied Medical Sciences, Darband St.
City
Tehran
Province
Tehran
Postal code
1971653313
Approval date
2023-03-05, 1401/12/14
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.837

Health conditions studied

1

Description of health condition studied

Multiple myeloma (MM) patients undergoing autologous hematopoietic stem cell transplantation

ICD-10 code

C90.0

ICD-10 code description

Multiple myeloma

Primary outcomes

1

Description

Regulatory T cell

Timepoint

Days +14 and +99 post-autologous transplantation

Method of measurement

Number of T regulatory cells (CD4, CD25, FOXP3) in peripheral blood mononuclear cells (PBMC) by using flow cytometry technique

Secondary outcomes

1

Description

Number and phenotype of CD8+ T cells

Timepoint

Day 99+ post-autologous transplantation

Method of measurement

Number and phenotype of CD8 + T cells in peripheral blood mononuclear cells using flow cytometry technique (CD8, CD28, PD1)

2

Description

IL-10, TGF-B, IFN-G

Timepoint

Day 99+ post-autologous transplantation

Method of measurement

Determining the serum levels of cytokines at day +99 post-autologous transplantation by using ELISA

Intervention groups

1

Description

Intervention group: Pentoxifylline group: Patients who underwent autologous transplantation receive Pentoxifylline 800 mg/d, orally as 2 divided daily doses, respectively from day +15 through day +98 post-transplant

Category

Treatment - Drugs

2

Description

Control group: Multiple myeloma patients undergoing autologous transplantation who do not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

BMT department of Taleghani Hospital

Full name of responsible person

Dr. Abbas Haji Fathali

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Shahid Arabi St., Yemen 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

-

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Grant name

-

Grant code / Reference number

-

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

No

Title of funding source

-

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Davood Bashash

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available