Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of zinc supplement on oxidative stress and inflammation markers in multiple myeloma patients undergo autologous hematopoietic stem cell transplantation compared with placebo

Protocol summary

Study aim

Determination of the level of markers and genes of oxidative stress and inflammation in patients undergoing autologous BMT under the influence of oral zinc supplementation in comparison with the placebo group

Design

This study is a double-blind, placebo-controlled clinical trial that will be randomized by using a block design method, and study participants are randomly divided into two groups of 20 people, Zinc and Placebo. In the first month after transplantation, the patients will receive three tablets of zinc gluconate or placebo. Zinc and copper Serum levels will be measured before intervention and on days 15 and 30 after HSCT. The expression of Nrf2, INrf2 (Keap1), SOD1, SOD2, NOX1, NOX2 genes as well as the levels of TNF-α and the activity of MDA, NO enzymes will be measured to determine the effect of oral zinc supplementation on gene expression, enzyme levels and measure inflammatory and oxidative stress markers.

Settings and conduct

Eligible patients will be selected from those referred to the BMT department of Taleghani Hospital for auto-HSCT. Patients enter the study after describing the objectives of the study and filling out the consent form.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: History of Multiple Myeloma; A complete response to treatment; Patients are candidates for AHST; have a health certificate. Exclusion Criteria: History of sensitivity to oral zinc supplement; The patients who have consumed oral zinc supplementation since three months before the transplantation; Zinc serum levels above 200mg/dl.

Intervention groups

Group 1: Patients with a history of multiple myeloma undergoing BMT who receive placebo. Group 2: Patients with a history of multiple myeloma undergoing BMT who receive zinc.

Main outcome variables

Expression of Nrf2, INrf2 (Keap1), SOD1, SOD2, NOX1, NOX2 genes; TNF-α cytokine; Activity of MDA, NO enzymes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211227053546N1**
Registration date: **2022-03-23, 1401/01/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-23, 1401/01/03**
Update count: **0**

Registration date

2022-03-23, 1401/01/03

Registrant information

Name

Nariman Mosaffa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 9970

Email address

mossafan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of zinc supplement on oxidative stress and inflammation markers in multiple myeloma patients undergo autologous hematopoietic stem cell transplantation compared with placebo

Public title
Zinc supplement effect on oxidative stress and inflammation markers in multiple myeloma patients undergo autologous hematopoietic stem cell transplantation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Complete response to treatment Lack of underlying disease Do not get any infection in the last three months, including COVID19 Age range 40 to 60 years Patients with a history of multiple myeloma
Exclusion criteria:
History of sensitivity to "zinc" oral supplement Serum levels above 200 mg/dl Patients who have taken oral supplements for three months before transplantation. People's unwillingness to collaborate in the study
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this randomization method, the size of the blocks is considered equal. The size of each block is 4, which includes 2 participants in the zinc group and 2 participants in the placebo group. The SNOSE method is used to perform randomization. Based on the sample size of the research, a number of 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. In order 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. 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. Random sequencing was performed by SAS software version 9.4
Blinding (investigator's opinion)
Double blinded
Blinding description
This clinical trial is performed in a double-blind method, which means the patient and the principal researcher are not aware of the patient's treatment. Therefore, to maintain blindness, the randomization list is not shown to the principal researcher. A statistician prepares the randomization list. The package evaluator provides a form containing either zinc or a placebo for each patient. Zinc and placebo tablets are the same color and shape but have different ingredients.
Placebo
Used
Assignment
Parallel
Other design features
In this study, based on similar studies and in consultation with its researchers, the amount of "zinc" in 30 days after transplantation was selected to be 90 mg daily

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences_ Medical school
Street address
Tehran - Shahid Chamran Highway Shahid Shahriari Square - Koodkiar Street - School of Medicine
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-02-09, 1400/11/20
Ethics committee reference number
IR.SBMU.MSP.REC.1400.728

Health conditions studied

1

Description of health condition studied
Patients with multiple myeloma who are candidates for stem cell transplantation.
ICD-10 code
C90
ICD-10 code description
Multiple myeloma and malignant plasma cell neoplasms

Primary outcomes

1

Description
Determination of genes(Nrf2-INrf2(Keap1)-SOD1,2-NOX1,2) expression
Timepoint
Before hematopoietic stem cell transplantation beginning and 15,30 days after transplantation
Method of measurement
In DNA extracted from peripheral blood mononuclear cells using Real-Time-PCR

2

Description
Determination of MDA-NO protein levels
Timepoint
Before hematopoietic stem cell transplantation beginning and 15,30 days after transplantation
Method of measurement
MDA assay by thiobarbituric acid method and NO assay by griess method

3

Description
Determination of TNF-a cytokine
Timepoint
Before hematopoietic stem cell transplantation beginning and 15,30 days after transplantation
Method of measurement
Assay of cytokines by ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who underwent autologous HSCT receive three tablets of "gluconate zinc" (each tablet containing 30 mg zinc elemental) daily after eating main meals for first 30 days post-HSCT
Category
Treatment - Drugs

2

Description
Control group: Patients who underwent autologous HSCT receive three tablets of "placebo" (similar to zinc supplements) daily after eating the main meals for first 30 days post-HSCT
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Educational Hospital, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Hajifathali
Street address
Arabian Street, End of Velenjak Street, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2303 1657
Email
hajifathali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahshid Mehdizadeh
Street address
Arabian Street, End of Velenjak Street, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2303 1657
Email
Mahshid_mehdizadeh@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
Nariman Mosaffa
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
School of medicine,Kodakyar alley, daneshjo blvd, velenjak,
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9970
Email
yasamaryan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Immunology Department, Medical School, Tarbiat Modares University
Full name of responsible person
Maryam Nikoonezhad
Position
PhD Candidate
Latest degree
Master
Other areas of specialty/work
Immunology
Street address
Department of Immunology,School of Medicine,Tarbiat Modarres University, Nasr Bridge,Jalal Al Ahmad Street.
City
Tehran
Province
Tehran
Postal code
14115111
Phone
+98 21 6606 7261
Email
maryam.nikoonezhad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Kasra Jahankhani
Position
Master student of Medical immunology
Latest degree
Bachelor
Other areas of specialty/work
Immunology
Street address
School of medicine,Kodakyar alley, daneshjo blvd, velenjak,
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9970
Email
Kasrajahankhanii@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
For ethical reasons, we have no plans to publish participants' data
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available