Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of oral zinc supplement and placebo effect in improving the T cells regeneration in patients undergoing autologous hematopoietic stem cell transplantation-clinical trial study

Protocol summary

Study aim
Effect of oral "zinc" supplementation on T cells reconstitution after autologous HSCT

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, and then one tablet daily for two months. Zinc and copper Serum levels will be measured before intervention and on days 30 and 90 after HSCT. TREC copy and RTE T cell, Tn, Tm cells number will be evaluated on days 30, 90, 180 after transplantation. In order to evaluate T cells' function, patients are monitored for one year after HSCT for viral infection (CMV, EBV) and relapse.

Settings and conduct
Eligible patients will be selected from those referred to the bone marrow transplant 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 autologous hematopoietic stem cell transplantation; Without comorbidity with heart, kidney, liver, lung, and digestive system disease. Exclusion Criteria: History of sensitivity to oral zinc supplement; The patients who have consumed oral zinc supplementation from 3 months before the transplant; Zinc serum levels above 200mg/dl.

Intervention groups
The intervention group, "Zinc Gluconate" 30 mg, and the control group, "placebo", will receive three tablets in the first thirty days post-HSCT (+1 to +30) and the following one tablet as maintenance dose will receive for sixty days (+31 to +90).

Main outcome variables
Recent Thymic Emigrant T cells number; sjTREC copies number

General information

Reason for update
The designed protocol has been confirmed

Acronym

IRCT registration information
IRCT registration number: **IRCT20191211045701N1**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**
Update count: **4**

Registration date
2020-06-12, 1399/03/23

Registrant information

Name
Ahmad Zavaran Hosseini

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral zinc supplement and placebo effect in improving the T cells regeneration in patients undergoing autologous hematopoietic stem cell transplantation-clinical trial study

Public title

The effect of oral "zinc" supplementation on the T cells reconstitution in patients undergoing autologous hematopoietic stem cell transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 40 to 60 years Patients with a history of multiple myeloma on complete response to treatment Patients are candidates for autologous hematopoietic stem cell transplantation Confirmation of the patient's heart, kidney, liver, lung, and digestive system health before hematopoietic stem cell transplantation by a specialist

Exclusion criteria:

History of sensitivity to "zinc" oral supplement Patients who have taken oral supplements for three months before transplantation. Serum levels above 200 mg/dl

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **4**

Before starting the HSCT process and 30,90,180 days after transplant

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 4.4

Blinding (investigator's opinion)

Double blinded

Blinding description

This clinical trial is performed in a double-blind method. This means that the patient and the main researcher are not aware of the treatment that the patient receives. Therefore, in order to maintain blindness, the randomization list is not shown to the main researcher. The randomization list is prepared by a statistician. 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 with 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 and 60 days later 30 mg daily.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Medical School of Tarbiat Modares University

Street address

Faculty of Medicine,Tarbiat Modares University,Nasr Bridge Intersection,Jalal Al-Ahmad Highway

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Province

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Postal code

111-14115

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.MODARES.REC.1398.195

Health conditions studied

1

Description of health condition studied
Patients with multiple myeloma who are candidates for stem cell transplantation.
ICD-10 code
C96
ICD-10 code description
Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue

Primary outcomes

1

Description
Number of Recent Thymic Emigrant T-cells in peripheral blood mononuclear cells (PBMC)
Timepoint
Before hematopoietic stem cell transplantation begging and 30, 90, 180 days after transplantation
Method of measurement
Using flow cytometry technique and specific RET T cells markers

2

Description
Determination of copy number of TREC (marker of thymus output) in peripheral blood mononuclear cells (PBMC)
Timepoint
Before hematopoietic stem cell transplantation begging and 30, 90, 180 days after transplantation
Method of measurement
In DNA extracted from peripheral blood mononuclear cells using Real-Time-PCR

Secondary outcomes

1

Description
Naive T cells number in the peripheral blood mononuclear cell population (PBMC)
Timepoint
Before the hematopoietic stem cell transplantation process and 30, 90 and 180 days after transplantation
Method of measurement
Using flow cytometry techniques and T cells specific markers

2

Description
Memory T cells number in the peripheral blood mononuclear cell population (PBMC)
Timepoint
Before the hematopoietic stem cell transplantation process and 30, 90 and 180 days after transplantation
Method of measurement
Using flow cytometry techniques and T cells specific markers

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 and one tablet of "gluconate zinc" is taken every night before bedtime from 31 to 90 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 and one tablet of "placebo" is taken every night before bedtime from 31 to 90 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tarbiat Modares University

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

2

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
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
Tarbiat Modares University

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Ahmad zavaran Hosseini

Position
Professor

Latest degree
Ph.D.

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Immunology

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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