Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of oral nutrition supplement (ONS) on nutritional and clinical status of patients undergoing autologous hematopoietic stem cell transplantation

Protocol summary

Study aim

Determining the effect of oral nutritional supplements on the nutritional and clinical status of patients undergoing autologous bone marrow transplantation

Design

The study is a randomized clinical trial, with a control group, phase 2 on 38 patients. The type of intervention in the treatment group is an oral nutritional supplement. The intervention will be for 21 days and the follow-up will be up to 90 days after the transplant. The control group will not receive any supplements.

Settings and conduct

The treatment group will receive an oral nutritional supplement containing 500 kcal of energy and 14-15% protein. The study will be conducted in Shariati Hospital. 250 cc of formula will be given to patients in the morning snack and before bedtime. The control group will not receive any supplements. The intervention lasts for 21 days and we will follow up with the patients until 90 days after the transplant. Blinding will not be done.

Participants/Inclusion and exclusion criteria

Patients with lymphoma or multiple myeloma are candidates for autologous bone marrow transplantation /Reluctance to cooperate

Intervention groups

The intervention in the treatment group will be an oral nutritional supplement of 500 kcal containing 14-15% protein. The formula will be given to patients in the amount of 250 ccs in the morning and before going to bed. The control group will not receive any supplements. The intervention will be carried out for 21 days and we will follow up with the patients until 90 days after the transplant.

Main outcome variables

Weight, appetite, hand grip strength, calf circumference, mid-arm circumference, malnutrition based on PG-SGA tool, oral mucositis, infection during hospitalization, graft failure, relapse after transplantation, number of days to platelet transplantation and neutrophils, readmission within 90 days post-transplant, and mortality up to 90 days post-transplant.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220208053971N2**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Hamed Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

hmohamadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-17, 1401/09/26

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral nutrition supplement (ONS) on nutritional and clinical status of patients undergoing autologous hematopoietic stem cell transplantation

Public title

The effect of oral nutrition supplement (ONS) on autologous hematopoietic stem cell transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lymphoma or multiple myeloma are candidates for autologous hematopoietic stem cell transplantation Age range 18-50 years

Exclusion criteria:

Reluctance to cooperate

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified block randomization will be performed based on the sex and age and using the site www.randomization.com. In this method, each group will be assigned one of the letters A and B, and randomization will be done in blocks with size of 4 . This will be done for sex (male and female) and age (18-35 and 35-50 years old). Within each class, patients will be randomly assigned to one of the two study groups in a 1: 1 ratio. The randomization process will be performed by someone outside the research team.

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 Tehran University of Medical sciences

Street address

Room 605, Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

141556117

Approval date

2022-10-28, 1401/08/06

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1401.017

Health conditions studied

1

Description of health condition studied

Lymphoma

ICD-10 code

C85.9

ICD-10 code description

Non-Hodgkin lymphoma, unspecified

2

Description of health condition studied

multiple myeloma

ICD-10 code

C90.0

ICD-10 code description

Multiple myeloma

Primary outcomes

1

Description

Weight

Timepoint

The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.

Method of measurement

Seca Scales

2

Description

Body mass index(BMI)

Timepoint

The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.

Method of measurement

Questionnaire and calculation

Secondary outcomes

1

Description
Rate of infection during hospitalization
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Medical record

2

Description
Recurrence rate after transplantation
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Medical record

3

Description
Severity of oral mucositis
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
According to the WHO oral toxicity criteria

4

Description
Number of readmissions after transplantation during three months
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Medical record

5

Description
The number of days it takes for neutrophil engraftment to occur.
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Complete Blood cell Count

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Description
The number of days it takes for platelet engraftment to occur.
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Complete Blood cell Count

7

Description
Graft Failure
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Based on medical records

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Description
Mortality rate up to three months after transplantation
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Based on medical records

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Description
Appetite
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Visual analog scale

10

Description
Hand grip strength
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Hand dynamometer

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Description
Mid-arm circumference
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.

Method of measurement
Seca tape measure

12

Description
Calf circumference
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Seca tape measure

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Description
Total energy intake
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Food record questionnaire & Analysis by N4 software

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Description
Protein intake
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Food record questionnaire & Analysis by N4 software

15

Description
Carbohydrate intake
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
food record questionnaire & Analysis by N4 software

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Description
Fat intake
Timepoint
The first stage, on the negative day 7 of transplantation, the second stage, positive 14 days after transplantation, and the third stage, 90 days after transplantation.
Method of measurement
Food record questionnaire & Analysis by N4 software

Intervention groups

1

Description
Intervention group: The type of intervention in the treatment group will be an oral nutritional supplement of 500 kcal, including carbohydrates, fat, protein, vitamins, and minerals. The formula will be given to patients in the amount of 250 ccs in the morning and bedtime snacks. The control group will not receive any supplements. The intervention will be carried out for 21 days and we will follow up with the patients until 90 days after the transplant.
Category
Other

2

Description
Control group: The control group will not receive any supplements.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Dr. Hamed Mohammadi
Street address
Kargar Shomali Street, Jalal-e-Al-e-Ahmad hwy
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1411713135
Phone
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Fax
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shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotoohi
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Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.
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Postal code
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Phone

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msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Hamed Mohammadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr, Hamed Mohammadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

Full name of responsible person

Sajedeh Habibi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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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

Due to the confidentiality of participant information, it is not possible to publish it.

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

Not applicable

Data Dictionary

Not applicable