Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Graft versus host disease prevention/reduction by microbiome and patient blood management in allogeneic hematopoietic stem cell transplant patients

Protocol summary

Study aim

Evaluation of whether probiotic use is associated with prevention/reduction of GVHD and predicting GVHD in these patients Determining the effect of using familact probiotic drug in preventing and predicting GVHD

Design

A randomized controlled clinical trial in 2 groups and randomized in two groups.On the one hand, blind

Settings and conduct

This treatment is performed in the transplant department of Taleghani Hospital in collaboration with the Iranian Blood Transfusion Organization- Intervention patients (n = 20) were given a probiotic capsule capsule daily before transplantation (-21 to transplant day) for 21 days and blood samples were collected in 5 CCs in 2 times. Indicates that Tregulatory testing and ST-2 and REG-3a plasma biomarkers will be tested. Each patient will be followed for up to 100 days.No control was used for the control group and only sampling would be performed on these two occasions

Participants/Inclusion and exclusion criteria

Patients who are candidates for allogeneic bone marrow transplant 1- Patient consent and consent provided with the approval of the Ethics Committee form 2- 20 to 50 years 3. The source of the transplanted tissue of all patients is peripheral blood stem cells 4 - The connective tissue for HLA is fully compatible with the patient's HLA 5. The prophylaxis diet should be the same to prevent their GVHD 6. All patients use blood and radiation products Exclusion criteria: 1. The patient's withdrawal from continuing study and drug use 2. The incidence of severe blood infection and severe diarrhea in patients 3. Fever above 38.5 degrees 4. Absolute neutrophil count less than 500 (ANC <500)

Intervention groups

Intervention group: Patients who have undergone bone marrow allogeneic transplantation and received a food-licensed probiotic drug as a supplement Control group: No medication

Main outcome variables

GVHD prevention, GVHD prediction,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190914044766N1**
Registration date: **2020-01-28, 1398/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-28, 1398/11/08**
Update count: **0**

Registration date

2020-01-28, 1398/11/08

Registrant information

Name

Ehsan Yazdandoust

Name of organization / entity

High institute for research and education in transfusion medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 4446 0620

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Graft versus host disease prevention/reduction by microbiome and patient blood management in allogeneic hematopoietic stem cell transplant patients

Public title
Graft versus host disease prevention/reduction by microbiome and patient blood management in allogeneic hematopoietic stem cell transplant patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Candidates for allogeneic bone marrow transplant who have been referred for transplantation to Taleghani Hospital for treatment of blood malignancies Age 20 to 50 years The source of the transplanted tissue of all patients is peripheral blood stem cells HLA transplanted tissue to be fully compatible with patient HLA (fully compatible with primary HLA A , B and DR-B1) The prophylaxis diet should be the same to prevent GVHD All patients use irradiated blood and products

Exclusion criteria:
Patients who did not have allogeneic bone marrow transplantation Patient dissatisfaction Having an infection or fever above 38.5 ° C before entering the study

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
The intervention group received 20 capsules of familact probiotic orally daily and the control group received no medication. Blood samples are taken from both groups twice

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided into control and intervention groups Based on random number table We assign a number to each patient based on the time patients visit and perform randomization using a random number table.

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 High Institute for Education and Research in Transfusion Medicine

Street address
ehran Province, Tehran, District 2, Hemmat Expy

City
Tehran

Province
Tehran

Postal code
115714665

Approval date
2019-12-16, 1398/09/25

Ethics committee reference number
IR.TMI.REC.1398.023

Health conditions studied

1

Description of health condition studied
graft versus host disease

ICD-10 code
D89.81

ICD-10 code description
Graft-versus-host disease

2

Description of health condition studied
acute graft versus host disease

ICD-10 code
D89.810

ICD-10 code description
Acute graft-versus-host disease

Primary outcomes

1

Description
Occurrence of graft-versus-host disease (GVHD)

Timepoint
They are followed up clinically for up to 100 days after transplantation

Method of measurement
Using clinical evidence that occurs in the patient and the

physician's opinion

2

Description
The grade and severity of graft-versus-host disease
Timepoint
They are followed up clinically for up to 100 days after transplantation
Method of measurement
Using clinical evidence that occurs in the patient and the physician's opinion

3

Description
The rate and percentage of regulatory T in patients
Timepoint
Day 7 and 28 after transplantation
Method of measurement
روش آزمایشگاهی فلوسایتومتری

4

Description
Plasma levels of reg3a and ST-2
Timepoint
Day 7 and 28 after transplantation
Method of measurement
ELISA Laboratory Method

Secondary outcomes

1

Description
Improve and reduce gastrointestinal complications
Timepoint
Up to 10 days after transplant
Method of measurement
Patient clinical statements

Intervention groups

1

Description
Intervention group: Intervention group:20 Patients reported for allogeneic bone marrow transplantation: who consume one day of graft probiotic capsule daily for 21 days before transplantation until the day of transplantation./It should be noted that familact is a probiotic and prebiotic compound containing 7 strains of beneficial bacteria (Lactobacillus, Bifidobacteria and Streptococcus thermophilus) plus Prebiotic Fructoaligosaccharide)
Category
Treatment - Drugs

2

Description
Control group: 20 patients reported for allogeneic bone marrow transplantation and not taking any additional medication
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Bone Marrow Transplantation Department of Taleghani Hospital
Full name of responsible person
DR Abbas Hajifathali
Street address
Taleghani Educational Hospital, Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
High Institute for Research and Education in Transfusion Medicine
Full name of responsible person
Mahtab Maghsudlu
Street address
High Institute for Research and Education in Transfusion Medicine, Shahid Hemmat, Next to Milad Tower
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Maghsudlu@ibto.ir
Web page address
https://tmi.ac.ir/
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
High Institute for Research and Education in Transfusion Medicine
Proportion provided by this source
80
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
high institute for research and education in transfusion medicine
Full name of responsible person
Ehsan Yazdandoust
Position
phd candidate
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome is added and published

When the data will become available and for how long

The publication begins after the paper is published after the research is completed

To whom data/document is available

Information will be made available to all researchers

Under which criteria data/document could be used

Use of published articles from this study , For more details and details, please contact the corespondent author of the paper published in this research

From where data/document is obtainable

Ehsan Yazdandoust yazdandouste@gmail.com 09107434515 Corresponding author of published research articles

What processes are involved for a request to access data/document

After contacting the information provider, the information will be made available to the applicant within two weeks. This will be the posting of the information after the articles are published

Comments

Most of the essential information was provided to the researchers by the publication of the article