

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of Beta Glucan and both of Beta Glucan and Lactobacillus Rhamnosus GG on immune system , nutritional status and side effects of chemotherapy in breast cancer patients

Protocol summary

Summary

Object of study: Determination the effect of beta glucan and both of beta glucan and lactobacillus rhamnosus GG on immune system, nutritional status and side effects of chemotherapy in breast cancer patients. Study design: random, double blind, control with placebo, one research center. Study population: breast cancer patients in stages 2 and 3 of disease randomly divided into 3 groups: 1- beta glucan(20 mg/d), 2- beta glucan(20 mg/d) with lactobacillus rhamnosus GG (2*10⁷ CFU) and control group will receive placebo. Study groups will receive capsules between two chemotherapies, during 21 days. Inclusion criteria: physician definitive diagnosis of breast cancer; receiving chemotherapy; no allergies to molds and yeasts; adequate bone marrow function; proper function of kidney; absence of other acute medical conditions; aged 20 years and older. Exclusion criteria: patient reluctance to participate in the study; pregnant women; lactating women; existence the acute medical illness. Sample size: 45 patients (15 patients in 3 groups). Study interventions: 1- beta glucan 2- beta glucan and lactobacillus rhamnosus GG. Intervention duration: 21 days, between 2 chemotherapies. Primary outcome: the effect of supplements on CBC, CD4, CD45RA, IL-4, IL-12. Secondary outcome: the effect of supplements on nutrition status and the quality of life in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212172017N10**
Registration date: **2013-02-10, 1391/11/22**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-10, 1391/11/22

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hematology Oncology Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Beta Glucan and both of Beta Glucan and Lactobacillus Rhamnosus GG on immune system , nutritional status and side effects of chemotherapy in breast cancer patients

Public title

The effect of Beta Glucan and both of Beta Glucan and Lactobacillus Rhamnosus GG on immune system , nutritional status and side effects of chemotherapy in breast cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: physician definitive diagnosis of breast cancer; receiving chemotherapy; the ability to drink at least 100 ml of water per day; life expectancy and survival at least 3 months; no allergies to molds and yeasts; adequate bone marrow function; proper function of kidney; absence of other acute medical conditions and aged 20 years and older. Exclusion criteria: patient reluctance to participate in the study; pregnant women; lactating women and existence the acute medical illness.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Tabriz-Golgasht Street-Tabriz University of Medical Sciences- Central Building Number 2-Third Floor- Research Vice-Chancellor

City

Tabriz

Postal code

Approval date

2013-01-07, 1391/10/18

Ethics committee reference number

91172

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant Neoplasm of Breast

Primary outcomes

1

Description

Improvement of Immune System

Timepoint

Immediately After the Intervention

Method of measurement

CBC,CD4,CD45,IL-4,IL-12

Secondary outcomes

1

Description

Improved Chemotherapy Side Effects

Timepoint

Immediately After the Intervention

Method of measurement

Questionnair

2

Description

Improved Nutrition Status

Timepoint

Immediately After the Intervention

Method of measurement

Anthropometric Assessment

Intervention groups

1

Description

Beta Glucan 10 mg, 2 tablets a day 21 days

Category

Treatment - Other

2

Description

Beta Glucan 10 mg, 2 tablets a day 21 days with Lactobacillus Rhamnosus GG (2*10⁷ CFU) for 21 days

Category

Treatment - Other

3

Description

Placebo
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ghazi Tabatabaye Hospital
Full name of responsible person
Dr. Alireza Ostad rahimi
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hematology Oncology Research Center, Tabriz
University of medical Sciences
Full name of responsible person
Dr. Jamal Eivazi
Street address
Tabriz, Ghazi Hospital, Hematology Oncology Research
Center
City
Tabriz
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Hematology Oncology Research Center, Tabriz
University of medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty