Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of probiotics administration on acute side effects of chemotherapy regimens in gastroesophageal cancer patients

Protocol summary

Study aim
The effects of probiotics administration on acute side effects of chemotherapy regimens in gastroesophageal cancer patients

Design
A randomized, parallel, with a control group, double-blinded, phase 3 of 42 patients. Rand software in Excel was used for randomization.

Settings and conduct
In the oncology ward of Rajaie hospital with a standard questionnaire, based CTCAE , double-blinded(patient and researcher)

Participants/Inclusion and exclusion criteria
Patients with gastroesophageal cancer stage 3,4 who had chemotherapy(dcf,folfox)-induced side effects and were older than 18 with first-grade tumor. Patients with severe systematic disease (such as heart, kidney, and liver) or previously had chemotherapy or were given antibiotics and probiotics were excluded.

Intervention groups
Patients with stage 3,4 esophageal cancer who receive dcf folfox will get probiotics till the end of their chemotherapy period and will be reviewed in comparison to the control group with a standard questionnaire.

Main outcome variables
Age, Sex, Cancer, Probiotic

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211024052857N1**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **prospective**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date
2021-11-08, 1400/08/17

Registrant information
Name
Alireza Tojjari
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-26, 1400/09/05

Expected recruitment end date
2021-12-26, 1400/10/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of probiotics administration on acute side effects of chemotherapy regimens in gastroesophageal cancer patients

Public title
The effects of probiotics administration on acute side effects of chemotherapy regimens in gastroesophageal cancer patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:

Patients with gastroesophageal cancer stage 3,4 who had chemotherapy(dcf,folfox)-induced side effects and were older than 18 with first-grade tumor.

Exclusion criteria:

Patients with severe systematic disease (such as heart, kidney, and liver) or previously had chemotherapy or were given antibiotics and probiotics.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned to receive either probiotic (n = 21) or nothing (control = 21) based on randomized block randomization and stratified randomization. Closed pockets were used to hide the randomization process, which was opened at the time of the patient's visit to minimize the gap between randomization and drug or control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses will be completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered pockets of capsules.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

West Booali st, Nabovat square, Karaj city

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Alborz

Postal code

3149969415

Approval date

2021-02-16, 1399/11/28

Ethics committee reference number

IR.ABZUMS.REC.1399.287

Health conditions studied

1

Description of health condition studied

Gastroesophageal cancers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of side effects of chemotherapy in patients with gastroesophageal cancers

Timepoint

Duration of chemotherapy

Method of measurement

Standard questionnaire based CTCAE

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be given probiotics (" DailyEast", Zist Takhmir) once a daily during their chemotherapy.

Category

Prevention

2

Description

Control group: Patients will be given their standard drugs during chemotherapy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Hospital

Full name of responsible person

Mojan Asadi

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Sponsors / Funding sources

1

Sponsor
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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
Karaj 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
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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable