

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of Kefir's Effects on Chemotherapy Complications in Colon Cancer Patients

Protocol summary

Study aim

Kefir's effect in reducing chemotherapy side effects in colon cancer patients

Design

Clinical trial with control group, parallel groups, randomized, and phase 3 on 40 patients. Random Allocation software was used for randomization.

Settings and conduct

This study investigates the effect of kefir on chemotherapy complications in patients at Imam Sajad Ramsar Hospital. For the kefir group, kefir consumption will begin at the time of the tenth chemotherapy session for six weeks. Until the end of the twelfth chemotherapy session, one glass (equivalent to 250 cc) will be consumed every other day, four days a week. Kefir is not used in the control group. All participants in both groups will be asked questions about side effects related to chemotherapy treatment, and the impact of kefir in the intervention group will be evaluated compared to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with stage 3 and/or 4 colon cancer who have undergone 12 chemotherapy sessions with FOLFOX injectable drugs. Exclusion criteria: consumption of probiotic, prebiotic, and synbiotic products within the past three months; alcohol consumption; patients who cannot complete the study period; and being lactose intolerant.

Intervention groups

Kefir group: kefir consumption Control group: no kefir consumption

Main outcome variables

Diarrhea, constipation, xerostomia, sleep disorders, nausea, weight loss, anorexia, flatulence, dysgeusia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230107057070N1**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

bahareh Lashtoo aghaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5509 1125

Email address

b.agmaee@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-12-27, 1402/10/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Kefir's Effects on Chemotherapy Complications in Colon Cancer Patients

Public title

Effect of kefir on the side effects of colon cancer chemotherapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with stages 3 and/or 4 colon cancer treated with injectable FOLFOX chemotherapy for 12 sessions
Exclusion criteria:
Consumption of probiotic, prebiotic, or synbiotic products in the last three months Alcohol consumption Patients incapable of completing the study period Lactose malabsorption

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
A block classification method will be used to allocate samples into two groups. The blocking process will be done using random allocation software. Based on random numbers generated by this software, samples will be analyzed. A control group and a kefir group will be studied according to this method.

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

Ramsar Campus ethics committee

Street address

Imam street, behind Imam sajad hospital

City

Ramsar

Province

Mazandaran

Postal code

4691710001

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.MAZUMS.RIB.REC.1401.051

Health conditions studied

1

Description of health condition studied

Colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

Primary outcomes

1

Description

Diarrhea

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

2

Description

Constipation

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

3

Description

Xerostomia

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

4

Description

Sleep disorders

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

5

Description

Nausea

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

6

Description

Weight loss

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

7

Description

Anorexia

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

8

Description

Flatulence

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

9

Description

Dysgeusia

Timepoint

At the beginning and end of the intervention

Method of measurement

Completing the questionnaire and being evaluated in person and by phone

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients with colon cancer in stages 3 and/or 4 who received injectable treatment with FOLFOX (Folinic acid, Fluorouracil, and Oxaliplatin) in 12-session chemotherapy courses. Kefir grains, industrially produced by Iran Ferment Company, Tehran, Iran, are added to milk pasteurized at 90-95°C for 10-15 minutes and cooled to 25-30°C. After the fermentation period, which lasts 24-48 hours, the seeds are separated by filtration. Kefir is stored in a container for one day, and then it is divided into bottles and stored in a refrigerator

at 4 degrees Celsius. And will be used within two weeks. All kefir prepared from the exact kefir grain are prepared under the same fermentation conditions to ensure that identical probiotics are present in the prepared kefir. Patients will take one glass equivalent to 250 CC for six weeks at the same time as the tenth chemotherapy session. They will do this four days a week and continue until the end of the twelfth chemotherapy session.

Category

Treatment - Other

2

Description

Control group: 20 patients with colon cancer in stages 3 and/or 4 who are treated with FOLFOX (folinic acid, fluorouracil, and oxaliplatin) in 12-session chemotherapy courses.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajad Hospital, Ramsar, Mazandaran, Iran

Full name of responsible person

Dr Shahrbano Keyhanian

Street address

Imam Street

City

Ramsar

Province

Mazandaran

Postal code

4691710001

Phone

+98 11 5522 2031

Email

b.aghaee@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mahsa Narenji

Street address

Imam st. Behind Imam Sajad Hospital. Ramsar Campus

City

Ramsar

Province

Mazandaran

Postal code

4691710001

Phone
+98 11 5509 1125

Email
b.aghaee@hotmail.com

Grant name
Mazandaran University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Bahareh Lashtoo Aghaee

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

Street address
Imam st. Behind Imam Sajad Hospital, Ramsar campus

City
Ramsar

Province
Mazandaran

Postal code
4691710001

Phone
+98 11 5509 1125

Email
b.aghaee@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Bahareh Lashtoo Aghaee

Position
Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work
Microbiology

Street address
Imam st, Behind Imam Sajad Hospital, Ramsar Campus

City
Ramsar

Province
Mazandaran

Postal code
4691710001

Phone
+98 11 5509 1125

Email
b.aghaee@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Bahareh Lashtoo Aghaee

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

Street address
Ramsar, Imam square. behind Imam sajad hospital

City
Ramsar

Province
Mazandaran

Postal code
4691710001

Phone
+98 11 5509 1125

Fax

Email
b.aghaee@hotmail.com

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
There is no further information

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

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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