

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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.ghaee@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 Shahrbanoo 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

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##### 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**  
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## Person responsible for scientific inquiries

**Contact**  
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Bahareh Lashtoo Aghaee  
**Position**  
Assistant Professor  
**Latest degree**

Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
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Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Bahareh Lashtoo Aghaee  
**Position**  
Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Microbiology  
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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**  
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