Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.aghaee@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 commitee

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 kefirs prepared from the exact kefir grain are prepared under the same fermentation conditions to ensure that identical probiotics are present in the prepared kefirs. 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
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Postal code
4691710001
Phone
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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
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Postal code
4691710001

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Email
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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
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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