Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of fermentable carbohydrates restricted diet on gut microbium and some inflammatory indices in patients with ulcerative colitis

Protocol summary

Study aim
The study aimed to investigate the effect of a low Fermentable Oligo-, Di-, and Mono-saccharydes and Polyols (FODMAP) diet on intestinal microbium and inflammation in patients with Ulcerative colitis.

Design
Hospital based controlled randomized clinical trial

Settings and conduct
Sampling will be done at Shariati hospital in Tehran, using available sampling method and based on inclusion criteria. Participants will be randomly stratified into binary blocks in terms of age, gender, body mass index, and drug type. Individuals in the intervention group will receive a low-FODMAP diet for 4 weeks. Participants in the control group will receive their usual diet without any modification, along with the specific recommendations, for 4 weeks.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1. Age over than 20 and under 60 years 2. Moderate ulcerative colitis 3. BMI 18.5 to 30 kg/m2 Patients with the following properties will not be included: 1. Changed in the type or dosage of their drugs over the past month 2. Suffered from other gastrointestinal diseases including cancers and infectious diseases 3. Pregnant or breastfeeding women or those with a decision for pregnancy in the near future 4. Use of antibiotics 5. Consumed pre- or pro-biotic products during the last two months 6. Use tobacco or smoke 7. Hospitalized in the last three months 8. Infection over the past 3 months 9. Suffering from any inflammation-promoting disease 9. Used multi-vitamin and mineral supplements during the past month

Intervention groups
Individuals in the intervention group will receive a low-FODMAP diet based their usual dietary intakes consistent with the specific recommendations of IBD patients. Individuals in the control group will receive their usual diet along with IBD specific recommendations.

Main outcome variables
Gut micribium, Serum inflammatory cytokines

General information

Reason for update

Acronym
FODMAP

IRCT registration information
IRCT registration number: **IRCT20181126041763N1**
Registration date: **2019-01-18, 1397/10/28**
Registration timing: **prospective**

Last update: **2019-01-18, 1397/10/28**
Update count: **0**

Registration date
2019-01-18, 1397/10/28

Registrant information

Name
Alireza Milajerdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8895 5805

Email address
amkhv@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of fermentable carbohydrates restricted diet on gut microbium and some inflammatory indices in patients with ulcerative colitis

Public title
Effect of flatulent carbohydrates restricted diet on gut microbium and inflammation in patients with ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over than 20 and under 60 years Moderate ulcerative colitis (ulcerative colitis diagnosis will be done by a gastroenterologist, using the Mayo score) who are on stable drug therapy. The scores of 6-8 will be considered as moderate UC. BMI 18.5 to 30 kg/m2

Exclusion criteria:
Changed in the type or dosage of their drugs over the past month Suffered from other gastrointestinal diseases including cancers and infectious diseases Pregnant or breastfeeding women or those with a decision for pregnancy in the near future Use of antibiotics Consumed pre- or pro-biotic products during the last two months Use tobacco or smoke Hospitalized in the last three months Infection over the past 3 months Suffering from any inflammation-promoting condition Used multi-vitamin and mineral supplements during the past month

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
participants will be matched in terms of age (20 to 40 and 40 to 60 years), gender (male/female), body mass index (18.5 to 24.9 and 25 to 30) and drug type (anti-inflammatory (steroidal/anti-TNF) and immunosuppressant) in blocks composed of two patients in each blocks. Then, participants in each block will be randomly allocated to intervention or control groups. In order to randomize assignment of participants, each person will be given a specific code. Then, a person outside the study will be asked to draw the code out of a pot using the lottery. Participant with the first draw out code will be allocated to the intervention group, and the second code as the control; in order the rest of participants will be randomly assigned to the two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
School of nutritional sciences and dietetics, Hojatdoost Ave., Naderi street, Keshavarz blv, Tehran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-10-03, 1397/07/11

Ethics committee reference number
IR.TUMS.VCR.REC.1397.441

Health conditions studied

1

Description of health condition studied
Inflammatory Bowel Disease (Ulcerative Colitis)

ICD-10 code
K51

ICD-10 code description
Ulcerative colitis

Primary outcomes

1

Description
Gut microbiota

Timepoint
Before Intervention and 4 weeks later

Method of measurement
PCR Method

Secondary outcomes

1

Description
Inflammation

Timepoint

Before intervention and 4 weeks later

Method of measurement

ELISA kit

Intervention groups

1

Description

Intervention group: Low-FODMAP diet in addition to general recommendations for IBD patients. Firstly, the basal metabolic rate (BMR) of the patients will be calculated using their age, sex, height and weight by the Harris Benedict formula. Then, daily energy requirement of each individual is calculated based on his/her physical activity when considering the thermogenic effect of foods (TEF). The macronutrient composition of this diet includes 55% energy from carbohydrates, 25% from fats, and 20% from proteins. Then, required values from each food group will be calculated. In each food group, food items with high FODMAP will be discarded, and the remaining foods will be divided into 6 meals/day, including 3 main meals and 3 snacks. Accordingly, a two-week meal menu will be set up that patients will continue it for two additional weeks (a total of 4 weeks).

Category

Treatment - Other

2

Description

Control group: General recommendations for patients with IBD including recommendations to have physical activity, timely disposing of feces, consumption of low-fat dairies and meats, consumption of vegetable oils, and reduction in consumption of refined sugars

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Alireza Milajerdi

Street address

Shariati Hospital, Jalal Ale Ahmad Street, Karegar Shomali street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Milajerdi

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

Ahmad Esmaillzadeh

Position

Professor

Latest degree

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Other areas of specialty/work

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Latest degree

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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

No additional information are available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Study protocol has been provided and will be published in a article.

When the data will become available and for how long

3 months after study begging

To whom data/document is available

Data will be available for all.

Under which criteria data/document could be used

For use in clinic or written a review article. For original studies, it will be permitted if they acknowledge our study personnel.

From where data/document is obtainable

Using Email, by author who are responsible for updating data

What processes are involved for a request to access data/document

After receiving application by the author who are responsible for updating data and following consultation with scientific consultant, data will be provided .

Comments