# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Oct 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)

**Phone**
+98 21 8895 5805

**Email address**
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**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Ahmad Esmaillzadeh

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**Province**

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**Email**

admin@sina.tums.ac.ir

**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**

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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**Street address**

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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**