

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the effect of modified specific carbohydrate diet on nutritional status, disease and quality of life in patients with ulcerative colitis

Protocol summary

Study aim

effect of modified specific carbohydrate diet on nutritional status, inflammation and quality of life in people with ulcerative colitis

Design

A clinical trial of a parallel type in which sufficient information about the objectives of the study, the type of intervention and the duration of the study will be explained to the volunteers who have the inclusion criteria. Before the start of the intervention, people will be grouped and matched based on gender (female/male) and the type of drug used.

Settings and conduct

Patients are randomly selected from those who visit in the hospital clinic. The diet delivered to control and intervention group patients is monitored during 6 weeks. At the beginning and end of the study, the main outcome variables are measured and compared to determine the impact of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1) Age between 20 and 60 years old 2) Suffering from ulcerative colitis with mild to moderate severity. Criteria for not entering the study 1) Changing the type and dosage of the drug consumed during the last month 2) Having other intestinal diseases or inflammatory and kidney diseases and diabetes 3) pregnancy or breastfeeding 4) use of antibiotics, or a anti-inflammatory or multivitamins supplements during the intervention and in the period of one month before the intervention 5) use of tobacco and drugs 6) history of hospitalization during The last three months

Intervention groups

The intervention group will receive food menus and essential recommendations of a specific modified carbohydrate diet to be followed for 6 weeks, and the patients of the control group will receive nutritional recommendations related to their disease to be followed

for a period of 6 weeks.

Main outcome variables

Measuring indicators of nutritional status, inflammation and quality of life

General information

Reason for update

Acronym

MSCD

IRCT registration information

IRCT registration number: **IRCT20170202032367N7**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Hossien Imani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

h-imani@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-22, 1402/02/02

Expected recruitment end date

2023-10-21, 1402/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of modified specific carbohydrate diet on nutritional status, disease and quality of life in patients with ulcerative colitis

Public title
Carbohydrate-restricted diet in inflammatory bowel disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age above 20 and less than 60 years Patients with mild to moderate ulcerative colitis Willingness to participate in the study
Exclusion criteria:
Changing the type of medicine used and its dosage during the last month Having other intestinal diseases (malignancies, infectious diseases) Suffering from other inflammatory diseases and kidney diseases and diabetes Pregnancy or breastfeeding Use of antibiotics, or use of pre- or probiotic products, or use of multivitamin and mineral supplements, or use of anti-inflammatory supplements such as w3 and curcumin during the intervention and in the one-month period before the intervention. Smoking and drug use History of hospitalization during the last three months

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

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Before starting the intervention, people will be placed in double blocks in terms of gender (male/female) and drug category. Random allocation of people placed in each block to intervention and non-intervention groups will be done. In order to randomly assign people to groups, each person is assigned a code and these codes are poured into a container. A person outside the study is then asked to draw codes from the container using a lottery. The first code will be assigned to the intervention group, the second code will be assigned to the control group, and the rest of the people will be randomly assigned to two groups.

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Faculty of Nutrition Sciences and Dietetics, Hojat Dost Alley, Khanaderi, Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-01-20, 1401/10/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.692

Health conditions studied

1

Description of health condition studied

Inflammatory bowel disease (ulcerative colitis)

ICD-10 code

Ulcerative

ICD-10 code description

K51

Primary outcomes

1

Description

Nutritional status

Timepoint

Before the intervention and 6 weeks later

Method of measurement

Anthropometric measurements including weight, height, and BMI calculation will be done and will be included in the questionnaire.

2

Description

inflammation

Timepoint

Before the intervention and 6 weeks later
Method of measurement
Eliza kit

3

Description

Quality of Life

Timepoint

Before the intervention and 6 weeks later

Method of measurement

Inflammatory bowel disease questionnaire

Secondary outcomes

1

Description

Complete blood cell count

Timepoint

Before the intervention and 6 weeks later

Method of measurement

Auto Analyzer device

Intervention groups

1

Description

Intervention group: People in the intervention group will receive a modified specific carbohydrate diet and essential tips during the diet to follow for 6 weeks.

Category

Treatment - Other

2

Description

Control group: People in the control group will follow their usual diet along with the nutritional recommendations related to their disease during these 6 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Helia Moharrami

Street address

Shariati Hospital, Jalal Al Ahmad Street, North Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411711335

Phone

+98 21 84901

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.hossein imani

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653911

Phone

+98 21 8163 3698

Email

vcr@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

Helia Moharrami

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 14, 15th Street (Shaheed Yagoubi), Olympic Village, Tehran

City

Tehran

Province

Tehran

Postal code

1485964751

Phone

+98 990 445 4402

Email

misshelia.1515@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hossien Imani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 44, Shahid Hojjat Doost Alley, Naderi St,
Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

0098 21 889900285

Email

h_imani@sina.tums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Helia Moharrami

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 44, Shahid Hojjatost Alley, Keshavarz Boulevard,
Naderi St

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 990 445 4402

Email

misshelia.1515@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available