Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2026

Investigating the effect of modified specific carbohydrate diet on disease severity, fecal calprotectin level and disability caused by the disease in people with ulcerative colitis.

Protocol summary

Study aim
Effect of Modified Specific Carbohydrate Diet on Disease Severity, Fecal Calprotectin Level and Disease-Related Disability 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 study1) 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
Measurement of disease severity indicators, fecal calprotectin level and disability caused by the disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170202032367N8**
Registration date: **2023-03-28, 1402/01/08**
Registration timing: **prospective**

Last update: **2023-03-28, 1402/01/08**
Update count: **0**

Registration date
2023-03-28, 1402/01/08

Registrant information

Name
Hossien Imani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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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 disease severity, fecal calprotectin level and disability caused by the disease in people with ulcerative colitis.

Public title
LJCarbohydrate-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
N/A
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
Faculty of Medicine - Tehran University of Medical Sciences (Research Ethics Committee)
Street address
Faculty of Nutrition Sciences and Dietetics, Hojat Dost Alley, Khanaderi, Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2023-02-11, 1401/11/22
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.753

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
Illness severity
Timepoint
Before the intervention and 6 weeks later
Method of measurement
9-point partial Mayo score questionnaire

2

Description
Fecal calprotectin levels
Timepoint
Before the intervention and 6 weeks later
Method of measurement

Eliza kit

3

Description
Disability due to illness
Timepoint
Before the intervention and 6 weeks later
Method of measurement
questionnaire

Secondary outcomes

empty

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.Before the start of the main intervention, all the selected people enter the Run-in period for two weeks, to collect complete information about the patients' food intake.During this period, 2 24-hour food reminders including two working days and one day off per week are completed. The physical activity of the patients will be recorded through the IPAQ questionnaire.All people will be asked not to change their physical activity and medication during the study compared to before the study and to avoid smoking during the study. The severity of the disease, fecal calprotectin level and disability caused by the disease will be evaluated at the beginning and end of the study.Important points during the prescribed modified specific carbohydrate diet:1- The consumption of any kind of bread prepared from wheat flour during this period is prohibited. 2- The use of wheat flour in the preparation of daily meals is prohibited. 3- It is forbidden to use any kind of cake, cookies, biscuits, etc. made from wheat flour. 4- It is forbidden to consume any kind of milk and products containing milk. 5- It is forbidden to consume all kinds of cheese except old cheeses that have There are small amounts of lactose.6- It is forbidden to consume all types of yogurt, except the leftover and old yogurts that contain small amounts of lactose. 7- In the cereal group, the use of oats, rice and quinoa is free. 8- There are no restrictions on the type of oils. 9- The consumption of food with preservatives is prohibited. 10- The consumption of all kinds of meats is free, except processed meats such as sausages, sausages, etc. 11. The consumption of artificial sweeteners and foods that have been prepared with these sweeteners is prohibited.
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.Before the start of the main intervention, all the selected people enter the Run-in period for two weeks, to collect complete information about the patients' food intake.During this period, 2 24-hour food reminders including two working days and one day off per week are completed. The physical activity of the patients will be recorded through the IPAQ questionnaire.All people will be asked not to change their physical activity and medication during the study compared to before the study and to avoid smoking during the study. The severity of the disease, fecal calprotectin level and disability caused by the disease will be evaluated at the beginning and end of the study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Mohammadreza Saboori
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Shariati Hospital, Jalal Al Ahmad Street, North Kargar 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
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Mohammadreza Saboori
Position
Masters student
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Person responsible for updating data

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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