Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of dietary modification programme (low-fat, low-carb and high-protein diet) on mood status, fatigue and quality of life in patients with ulcerative colitis

Protocol summary

Study aim

The aim of the current study was to evaluate the effects of dietary modification programme (low-fat, low-carb and high-protein diet) on fatigue, mood status, quality of life and lipid profile of ulcerative colitis patients during remission phase.

Design

This was a parallel group, randomized controlled trial Which has been performed on 80 patients with ulcerative colitis. Blocked randomization has been used for randomization.

Settings and conduct

We consecutively evaluated patients with suspect of ulcerative colitis in the inflammatory bowel disease center, Salamat clinic, Isfahan University of Medical Sciences, Isfahan, Iran. Subjects were admitted directly in our inflammatory bowel disease clinic or referred from other general medicine or gastroenterology clinics located in Isfahan city. Patients who were assigned to the intervention group participated in a 3-months dietitian-led dietary modification programme (low-fat, low-carb and high-protein diet). Patients randomized to the control group received routine care at the inflammatory bowel disease center.

Participants/Inclusion and exclusion criteria

Patients aged 18–80 years with a confirmed diagnosis of ulcerative colitis by gastroenterologist were eligible for inclusion. Subjects with dose changes of azathioprine, mercaptopurine, methotrexate, or biologics in the preceding 12 weeks; oral antibiotics, probiotics, prebiotics or especial diet in the preceding 8 weeks were excluded.

Intervention groups

Patients who were assigned to the intervention group participated in a 3-months dietitian-led dietary modification programme (low-fat, low-carb and high-protein diet). Patients randomized to the control group received routine care at the inflammatory bowel disease center.

Main outcome variables

Mood status, fatigue and quality of life are the main outcomes of this study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150304021342N2**
Registration date: **2020-05-23, 1399/03/03**
Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**
Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

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Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

2019-11-22, 1398/09/01

Actual recruitment end date

2020-04-19, 1399/01/31

Trial completion date

2020-04-24, 1399/02/05

Scientific title

The effects of dietary modification programme (low-fat, low-carb and high-protein diet) on mood status, fatigue and quality of life in patients with ulcerative colitis

Public title

Effect of low-fat, low-carb and high-protein diet in ulcerative colitis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18–80 years Confirmed diagnosis of ulcerative colitis by gastroenterologist

Exclusion criteria:

Subjects with dose changes of azathioprine, mercaptopurine, methotrexate, or biologics in the preceding 12 weeks Consumption of probiotics, prebiotics or following especial diet in the preceding 8 weeks

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A blocked randomization method with randomly permuted blocks sizes 4 was used to assign each patients to an intervention or control group, to guarantee recruitment balance between the 2 groups and avoid possible risk for selection bias. Depending on age and gender, individuals are placed in blocks of four and are placed in one of the intervention and control groups using a table of random numbers.

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 Isfahan University of Medical Sciences

Street address

Hezarjrib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.065

Health conditions studied

1

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Mood status

Timepoint

At baseline and after 12 weeks

Method of measurement

Depression, Anxiety, Stress-21 questionnaire

2

Description

Fatigue

Timepoint

At baseline and after 12 weeks

Method of measurement

Fatigue Severity Scale

3

Description

Quality of life

Timepoint

At baseline and after 12 weeks

Method of measurement

36-Item Short Form Survey

Secondary outcomes

1

Description
Lipid profile
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

Intervention groups

1

Description
Intervention group: Patients who were assigned to the intervention group participated in a 3-months dietitian-led dietary modification programme (low-fat, low-carb and high-protein diet). Participants were provided dietary guidelines in the form of an educational booklet and dedicated diet. The dietary guidelines of dietary modification programme primarily focused on the reduction of ulcerative colitis symptoms and nutritional deficiency risks. The provided guidelines endeavored to consolidate the existing documents as well as existing guidelines on diet and ulcerative colitis. The dietary modification programme consisted of recommendation that participants eat often and little (4-6 times per day), consume foods at a balanced temperature, decrease consumption of spicy foods, decrease excess intake of fat, decrease simple carbohydrate and drink adequate fluids. Moreover, increase good quality protein and eliminate dairy products in the presence of lactose intolerance. Furthermore, it included avoidance of margarine, limiting alcohol, caffeine and commercially prepared foods including fast foods, ready meals and canned foods.
Category
Treatment - Other

2

Description
Control group: Patients randomized to the control group received routine care at the inflammatory bowel disease center. Usual dietary advice included general oral and written information about healthy food choices based on the Healthy Eating Plate with 50–60% carbohydrates, 15–20% protein and 30% total fat. This composition was more parallel to the Iranian dietary pattern.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Salamat Clinic
Full name of responsible person
Babak Tamizifar
Street address
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person

Babak Tamizifar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Major part of information will be available for population
When the data will become available and for how long
12 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
To conduct similar studies
From where data/document is obtainable
Babak Tamizifar
What processes are involved for a request to access data/document
The data will send as soon as possible, after receiving the request
Comments