Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Gluten-free Regimen on the Quality of Life and Disease Severity of Ulcerative Colitis Patients; A Randomised Controlled Clinical Trial

Protocol summary

Study aim
Evaluation of the effect of Gluten-free regimen on the quality of life and disease severity among patients with ulcerative colitis

Design
Twenty-six cases who are eligible for enrollment in our project will be randomized in the intervention (gluten-free regimen) or control (regimen with gluten) using block randomization method. The regimen will be followed for 6 weeks.

Settings and conduct
This study will be performed in the department of gastroenterology and hepatology of Imam Khomeini hospital as a triple-blind randomized controlled-clinical trial.

Participants/Inclusion and exclusion criteria
All patients with at least 18-year-old of age who suffers from mild or moderate ulcerative colitis will be included in our project. Patients who suffer from severe type or inactive phase of ulcerative colitis, have a history of surgery due to IBD, using biological medications or those do not complete study protocol, will be excluded from the study.

Intervention groups
Bread with and without gluten will be given to patients in control and intervention groups respectively. All patients will be advised to use of a 26 gluten-free regimen.

Main outcome variables
Disease severity; quality of life; Inflammation markers (ESR, CRP, FEcal Calprotectin)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190523043680N1**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **registered_while_recruiting**
Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date
2019-06-15, 1398/03/25

Registrant information

Name
Foroogh Alborzi avanaki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6658 1650

Email address
falborzi@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Gluten-free Regimen on the Quality of Life and Disease Severity of Ulcerative Colitis Patients; A Randomised Controlled Clinical Trial

Public title
Effect of Gluten-free Regimen on Ulcerative Colitis Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with at least 18 year-old of age who suffers from mild or moderate ulcerative colitis
Exclusion criteria:
Patients who suffering from severe type or inactive phase of ulcerative colitis Has a history of surgery due to IBD Using biological medications Those does not complete study protocol

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
We use the blocked randomization method to balance the number of cases in each group of study. To prevent any possible anticipation, we will consider each block with different size. Interventions (regimen with and without gluten) is determined with A or B written on a paper putting in a closed envelope. Hence physicians cannot understand the type of interventions. (Allocation Concealment)

Blinding (investigator's opinion)
Triple blinded

Blinding description
The produced bread (with or without gluten) has been sent to patients by The representative of the pharmaceutical company. Accordingly, this is only the representative of the pharmaceutical company that is aware of the true types of intervention which makes our study as a tripe blind one. Nutritionists give consults to the patients through a one-hour session and ask all of them to prevent the use of any regimen containing gluten. Additionally, all patients can use a training pamphlet. The pharmaceutical company produces two types of bread which are similar regarding form, their package, and all other characteristics except for the existence of gluten. Hence, we can have a good option for placebo in our study. One type of produced bread is gluten-free (for the intervention group) and another one has 9 grams of gluten (for the placebo group).

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
Tehran University of Medical Science, Qods Avenue, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-01-28, 1397/11/08

Ethics committee reference number
IR.TUMS.IKHC.REC.1397.297

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
Disease Severity

Timepoint
Disease severity is measured in two times . (at starting the study and ending of it which is after 6 weeks of receiving the regimen by patients)

Method of measurement
With questionnaire of Simple Clinical Colitis Activity Index (SCCAI)

2

Description
Quality of Life

Timepoint
Quality of life of patients is measured in two times . (at starting the study and ending of it which is after 6 weeks of receiving the regimen by patients)

Method of measurement
With Persian version of IBD-Q

3

Description
Inflammation markers (ESR, CRP and Fecal Calprotectin)
Timepoint
Inflammation markers of patients is measured in two times . (at starting the study and ending of it which is after 6 weeks of receiving the regimen by patients)
Method of measurement
Routine laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The produced bread without gluten is sent to patients in the control group by the representative of the producer company (Sahar bread company). Nutritionists give consults to the patients through a one-hour session and ask all of them to prevent the use of any regimen containing gluten. Additionally, all patients can use a training pamphlet. The company produces two types of bread which are similar regarding form, their package, and all other characteristics except for the existence of gluten. Hence, we can have a good option for placebo in our study. One type of produced bread has gluten used in the control group.
Category
Treatment - Other

2

Description
Control group: The produced bread with 9 grams gluten is sent to patients in the intervention group by the representative of the producer company (Sahar bread company). Nutritionists give consults to the patients through a one-hour session and ask all of them to prevent the use of any regimen containing gluten. Additionally, all patients can use a training pamphlet. The company produces two types of bread which are similar regarding form, their package, and all other characteristics except for the existence of gluten. Hence, we can have a good option for placebo in our study. One type of produced bread is gluten-free which used in the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Gastroenterology and Hepatology of Emam Khomeini Hospital
Full name of responsible person
Reza Hadi
Street address
Department of Gastroenterology and hepatology, Emam Khomeini Hospital, Keshavarz Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Deputy of Research and Technology in Tehran University of Medical Sciences, 6th Floor, Central Building, Qods Street, Keshavarz Blvd
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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
Reza Hadi

Position
Fellowship of gastroenterology and hepatology

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Position
Fellowship of gastroenterology and hepatology

Latest degree
Specialist

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Person responsible for updating data

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Position
Fellowship of gastroenterology and hepatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Study Protocol together with the Statistical Analysis Map, Informed consent from, Participant Data, and report of the clinical study will be published after the end of the study. All of the items can be available except those which can help to identify patients.

When the data will become available and for how long
Data will be available together with the published paper of the study. After this, there will be no limitation for accessing data.

To whom data/document is available
There will be no limitation for accessing our data for anybody.

Under which criteria data/document could be used
Our data can be used for future studies like individual meta-analyses. Data will be available in the published paper of our study.

From where data/document is obtainable
Data will be available in the published paper of our study.

What processes are involved for a request to access data/document
There is no need for any request. Data will be available in the published paper of our study.

Comments
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