

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of saffron supplement on Antioxidative Status and Activity illness in patients with Ulcerative colitis

Protocol summary

Study aim

The effect of saffron supplementation on Antioxidative Status and activity illness in patients with Ulcerative colitis

Design

The current study is designed as a randomized clinical trial. In this research, 96 eligible patients referring to Colorectal Research Center of Rasoul-e-Akram Hospital, Tehran were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

In this study, patients with Ulcerative colitis referring to Hazrat Rasoul-e-Akram Hospital, who according to inclusion criteria and exclusion criteria, have the criteria to participate the study, would be asked to complete a written informed consent form. Individuals will be randomly assigned to receive intervention or placebo. Then, at the beginning and at the end of the study, 10 cc of fasting blood will be drawn. The level of TAC, SOD, GSH, MDA will be measured. At the beginning and the end of the study, anthropometric measurements and personal information questionnaires, activity illness, physical activity, and 24-hour recall are filled through interview.

Participants/Inclusion and exclusion criteria

The inclusion criteria of study are: Having the consent and Willingness to participate in study, age 18 and above. Also, the non-criteria of study include: changing the type and dosage of the drug over the past month, the incidence of other autoimmune diseases, pregnancy or lactation in women, the use of glucocorticosteroids over the past month and non-compliance with treatment (less than %80).

Intervention groups

In current study, from 96 patients with Ulcerative colitis, 48 patients in the intervention group will receive 1 daily tablet containing 100 mg of saffron and 48 patients in

the control group will use 1 daily placebo tablet containing Maltodextrin for 8 weeks.

Main outcome variables

activity illness; TAC; SOD; GSH; MDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N21**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of saffron supplement on Antioxidative Status and Activity illness in patients with Ulcerative colitis

Public title
The effect of saffron supplement on patients with Ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The willingness to voluntarily participate in the study The diagnosis of ulcerative colitis in the mild to moderate phase by the physician The consumer of only one of the drug groups 5 -Amino salicylic acid (Pentasa, Mesalazine or Asacol), as well as azathioprine BMI greater than 18.5 and less than 30
Exclusion criteria:
Changing the type and dosage of the drug over the past month The incidence of other autoimmune diseases, cancer The use of multi vitamin-mineral supplements, antioxidants, and also the use of anticoagulants, blood cholesterol lowering drugs, anti-TNF drugs, and glucocorticosteroids over the past month Pregnancy or lactation in women Non-compliance with treatment (less than 80%)

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 96 subjects, 24 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug boxes that is generated by the software. Participants will enter based on the sequence produced into study and the drug packets with code registered will allocate to the individual. Therefore, before participants selection, they will be unaware of the type of intervention that will receive, as well as a random sequence produced during the study will be immune from prediction.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to performing the double-blinded of study, before study beginning, the canisters containing saffron tablets can be provided by someone other than the researcher, and the placebo tablets in appearance are similar to the saffron tablets and the researcher are not be aware about the allocation of studied subjects in each group during the evaluation of the studied outcomes until the end of the intervention period.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Science
Street address
Iran University of Medical Science, Hemmat Express way
City
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Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-02-12, 1396/11/23

Ethics committee reference number
IR.IUMS.REC 1396.9511468003

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
Total Antioxidant Capacity (TAC)

Timepoint
Before the intervention and two months later of intervention

Method of measurement

Concentration of TAC in serum using ELISA kit.

2**Description**

Superoxide dismutase (SOD)

Timepoint

Before the intervention and two months later of intervention

Method of measurement

Concentration of SOD in serum using ELISA kit.

3**Description**

Malondialdehyde (MDA)

Timepoint

Before the intervention and two months later of intervention

Method of measurement

Concentration of MDA in serum using ELISA kit.

4**Description**

Glutathione (GSH)

Timepoint

Before the intervention and two months later of intervention

Method of measurement

Concentration of GSH in serum using ELISA kit.

5**Description**

activity illness

Timepoint

Before the intervention and two months later of intervention

Method of measurement

Using the SCCAI-Q questionnaire

Secondary outcomes**1****Description**

Body Mass Index

Timepoint

Before the intervention and two months later of intervention.

Method of measurement

Using the ratio of weight (kilogram) to the square of height (meter).

2**Description**

Weight

Timepoint

Before the intervention and two months later of intervention.

Method of measurement

Using the digital scale.

Intervention groups**1****Description**

Intervention group: Daily intake of one saffron tablet (100 mg) for 8 weeks (2 months).

Category

Treatment - Other

2**Description**

Control group: Daily intake of one placebo tablet (containing Maltodextrin) for 8 weeks (2 months)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Colorectal Research Center of Rasoul-e-Akram Hospital, Tehran

Full name of responsible person

Amir Hossein Faghihi Kashani

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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
Iran 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
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document

Only a section of the data, such as primary outcomes information or the like, will be shared.

When the data will become available and for how long

Access period start 6 months after results publishing.

To whom data/document is available

The obtained data from current study will be available only for working researchers in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the published papers from this study, the obtained data will be available to the researchers for

further analysis.

From where data/document is obtainable

Applicants can be communicated to correspond author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of Public Health, Iran university of Medical Sciences, Hemat Express way, Tehran Cell phone:+98 21 8670 4743 Email:vafa.m@iums.ac

What processes are involved for a request to access data/document

Applicants will be given access to the obtained data from current study by sending an email to the correspond author.

Comments