# 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 measurments 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**
Mohammad Reza Vafa

**Name of organization / entity**
Iran University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8670 4734

**Email address**
vafa.m@iums.ac.ir

**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**

Tehran

**Province**

Tehran

**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
**Street address**
Niyayesh St., Satarkhan St.
**City**
tehran
**Province**
Tehran
**Postal code**
1445613131
**Phone**
+98 21 6655 4790
**Email**
ahfaghihi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Seyed Kazem Malakouti
**Street address**
Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535

**Phone**
+98 21 86701
**Email**
malakoutik@yahoo.com

**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**

**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Mohammadreza Vafa
**Position**
PhD of Nutrition science
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehranan University of Medical Sciences
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 8670 4743
**Email**
vafa.m@iums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Mohmmadreza Vafa
**Position**
PhD of Nutrition science
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Nutrition Department, School of Public Health, Iran University of Medical Sciences, Hemat Express way, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 8670 4743
**Email**
vafa.m@iums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Mohammadreza Vafa
**Position**
PhD of Nutrition science
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Nutrition Department, School of Public Health, Iran University of Medical Sciences, Hemat Express way, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 8670 4743
**Email**
vafa.m@iums.ac.ir

## 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 publicated 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**