Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Aug 2022

The effect of Saffron supplementation on inflammatory markers and Quality of life in patients with Ulcerative Colitis

Protocol summary

Study aim
The effect of Saffron supplementation on inflammatory markers and Quality of life in patients with Ulcerative Colitis

Design
The current study is designed as a randomized clinical trial. In this research, 100 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 inflammatory factors IL-10, TNF-α, hs-CRP, ESR will be measured. At the beginning and the end of the study, anthropometric measurements and personal information questionnaires, Quality of life, physical activity, and 24-hour recall are filled through interview. 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.

Participants/inclusion and exclusion criteria
The inclusion criteria of study are: Having the consent and Willingness to participate in the study, age 18 and above, BMI greater than 18.5 and less than 30, and each of the two sexes. 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, cancer, pregnancy or lactation in women, 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 and non-compliance with treatment (less than %80).

Intervention groups
In current study, from 100 patients with ulcerative colitis, 50 patients in the intervention group will receive one daily tablet containing 100 mg saffron after meal for 8 weeks. While, 50 patients in the control group will use one daily placebo tablet containing maltodextrin for 8 weeks.

Main outcome variables
Quality of life; TNF-α; IL-10; ESR; NF-kB

General information

Reason for update

Acronym
IRCT registration information
IRCT registration number: IRCT20120415009472N18
Registration date: 2018-03-23, 1397/01/03
Registration timing: prospective

Last update: 2018-03-23, 1397/01/03
Update count: 0

Registration date
2018-03-23, 1397/01/03

Registrant information
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Naheed Aryaeian
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-03, 1397/01/14
Expected recruitment end date
2019-09-05, 1398/06/14
Actual recruitment start date
2018-04-05, 1397/01/16
Actual recruitment end date
2019-09-08, 1398/06/17
Trial completion date
empty

Scientific title
The effect of Saffron supplementation on inflammatory markers and Quality of life in patients with Ulcerative Colitis

Public title
Effect of Saffron supplementation on ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The willingness to voluntarily participate in the study 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 The diagnosis of ulcerative colitis in the mild to moderate phase by the physician

Exclusion criteria:
Changing the type and dosage of the drug over the past month The incidence of other autoimmune diseases, cancer Pregnancy or lactation in women 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 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: 100
More than 1 sample in each individual
Number of samples in each individual: 0
Before treatment- After treatment
Actual sample size reached: 90
More than 1 sample in each individual

Actual sample size in each individual: 0
Before treatment- After treatment

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 100 subjects, 25 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 Sciences
Street address
Sheikh Fazlolah Noori, Hemmat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-02-27, 1396/12/08
Ethics committee reference number
IR.IUMS.REC 1396.31960
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
IL-10
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Concentration of IL-10 in serum using ELISA kit.

2
Description
NF-kB
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
NF-kB activity in peripheral blood cells

3
Description
Quality of Life
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Using the IBDQ-9 questionnaire

4
Description
hs-CRP
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Concentration of IL-10 in serum using ELISA kit.

Secondary outcomes

1
Description
Weight
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Using the digital scale.

2
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).

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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Full name of responsible person
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Grant name
Grant code / Reference number
Iran University of Medical Sciences
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

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Naheed Aryaeian
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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
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:n-aryaeian@sina.tums.ac.ir

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