Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of coenzyme Q10 efficacy on some of inflammatory factors and oxidative stress status, disease activity index and quality of life in patients with ulcerative colitis

Protocol summary

Study aim

1- Determination and comparison of the effects of coenzyme Q10 and placebo on the serum concentration of inflammatory factors (IL-10 and IL-17) in patients with ulcerative colitis. 2- Determination and comparison of the effects of coenzyme Q10 and placebo on the activity of NF-kB and Nrf2 in patients with ulcerative colitis. 3- Determination and comparison of co-enzyme Q10 and placebo effects on serum concentration of AMPs (hBD2 and cathelicidin LL-37) in patients with ulcerative colitis 4. Determination and comparison of coenzyme Q10 and placebo effect on microRNA-146a expression in patients with ulcerative colitis. 5- Determination and comparison of coenzyme Q10 and placebo on the quality of life in patients with ulcerative colitis.

Design

The current study is designed s a randomized clinical trial.In this research, 50 eligible patients referring to Colorectal Research Center of Rasoul-e-Akram Hospital, Tehranwere 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

This study was designed to determine the effect of coenzyme Q10 supplementation on serum inflammatory factors and oxidative stress, antimicrobial peptides, microRNA-146a expression and quality of life in ulcerative colitis patients as a double blinded randomized clinical trial. This study is performed on 100 patients with ulcerative colitis referring to Rasoul-e-Akram Hospital in Tehran. Studied participants are randomly divided to two groups of intervention and control which consuming 2 coenzyme Q10 capsules per day and 2 placebo capsules containing rice flour for 8 weeks, respectively. In order to performing the double-blinded of study, before study beginning, the canisters containing CoQ10 capsule can be provided by someone other than the researcher, and the placebo capsules in appearance are similar to the CoQ10 capsules 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: 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.

Intervention groups

In current study, from 100 patients with ulcerative colitis, 50 patients in the intervention group will receive two daily capsules containing 100 mg of pure coenzyme Q10 (Health Burst, USA) after meal for 8 weeks. While, 50 patients in the control group will use two daily placebo capsules containing rice flour for 8 weeks.

Main outcome variables

IL-10 ;IL-17; NF-kB; hBD2; Nrf2; cathelicidin LL-37; microRNA-146a; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N17**
Registration date: **2017-12-30, 1396/10/09**
Registration timing: **prospective**

Last update: **2017-12-30, 1396/10/09**

Update count: **0**

Registration date

2017-12-30, 1396/10/09

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of coenzyme Q10 efficacy on some of inflammatory factors and oxidative stress status, disease activity index and quality of life in patients with ulcerative colitis

Public title

Effect of coenzyme Q10 supplementation on ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The willingness to voluntarily participate in the study The definitive diagnosis of ulcerative colitis by using histological studies of mucosal colon, rectum, and jejunium biopsy by the physician in the mild to moderate phase, The consumer of only one of the drug groups 5 - Amino salicylic acid (Pentasa, Mesalazine or Asacol), as well as azathioprine An age 18 and above BMI greater than 18.5 and less than 30 Each of the two sexes

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

Age

From **18 years** old to **79 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

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 CoQ10 capsule can be provided by someone other than the researcher, and the placebo capsules in appearance are similar to the CoQ10 capsules 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

Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway

City

Tehran

Province
Tehran
Postal code
1449614535
Approval date
2017-10-16, 1396/07/24
Ethics committee reference number
IR.IUMS.REC 1396.31412

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
IL-17
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Concentration of IL-17 in serum using ELISA kit.

3

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

4

Description
Nrf2
Timepoint
Before the intervention and two months later of intervention
Method of measurement
Nrf2 activity in peripheral blood cells.

5

Description
hBD2
Timepoint
Before the intervention and two months later of intervention
Method of measurement
Concentration of hBD2 in serum using ELISA kit.

6

Description
cathelicidin LL-37
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Concentration of cathelicidin LL-37 in serum using ELISA kit.

7

Description
microRNA-146a
Timepoint
Before the intervention and two months later of intervention
Method of measurement
microRNA-146a expression levels in serum using kit.

8

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

3

Description
Waist circumference
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
Distance of the last rib with iliac bone using tape meter.

4

Description
Hip circumference
Timepoint
قبل از شروع مداخله و دو ماه بعد از شروع مداخله
Method of measurement
The largest hip circumference using the tape meter.

5

Description
Waist–hip ratio
Timepoint
Before the intervention and two months later of intervention.
Method of measurement
The result of dividing the waist circumference into the hip circumference.

Intervention groups

1

Description
Intervention group: Daily intake of two CoQ10 capsules (100 mg) for 8 weeks (2 months).
Category
Treatment - Other

2

Description
Control group: Daily intake of two placebo capsules (containing rice flour) for 8 weeks (2 months)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
مرکز تحقیقات کولورکتال بیمارستان حضرت رسول اکرم (ص) تهران
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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

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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 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