Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Selenium supplementation on remission rate, serum levels of Interleukins 10, 17 and SIRT1 and PGC-1a gene expression and Quality of Life in patients with ulcerative colitis: Double-Blind RCT

Protocol summary

Study aim
The effect of selenium supplementation on remission rate, serum levels of interleukins 10, 17 and SIRT1 and PGC-1a gene expression and quality of life in patients with ulcerative colitis

Design
Two arm parallel group randomized double blind trial

Settings and conduct
Patients with mild-to-moderate active UC will be recruited between 2019-2020 from Rasoul-Akram medical center in Tehran, Iran. All 100 included patients will be randomized to receive 1 capsule a day of placebo or selenium for a duration of 10 wk. Each selenium capsule contained 200 micro gram of selenomethionine. Blood sampling, anthropometric measurements and related questionnaires will be done at baseline and at the end of the study.

Participants/Inclusion and exclusion criteria
Patients with age: 18≤ years who have a confirmed endoscopic and histologic diagnosis of UC and active mild-to-moderate UC , 30<BMI ≥18/5 will be recruited. The onset of some diseases, pregnancy or lactation in women, the use of multi-vitamin - Mineral supplements, omega-3, polyphenols and antioxidants, and some drugs (statins), NSAIDs, aspirin and etc during one previous month are excluded criteria of the study.

Intervention groups
200 microgram selenium /day

Main outcome variables
percentage of patients in clinical remission at the end of treatment, defined as SCCAI score [Simple Clinical Colitis Activity Index]

General information

Reason for update
sample size change

Acronym

IRCT registration information
IRCT registration number: **IRCT20091114002709N51**
Registration date: **2019-03-11, 1397/12/20**
Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**
Update count: **1**

Registration date
2019-03-11, 1397/12/20

Registrant information

Name
Farzad Shidfar

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8862 2755

Email address
shidfar.f@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-06, 1398/01/17

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Selenium supplementation on remission rate, serum levels of Interleukins 10, 17 and SIRT1 and PGC-1a gene expression and Quality of Life in patients with ulcerative colitis: Double-Blind RCT

Public title

The effect of Selenium supplementation n patients with ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Volunteering participation in the study The definitive diagnosis of injured colitis by using histological methods on mucosal biopsy of the colon, rectum and jejunium by the physician in the mild to moderate phase The consumer of only one of the 5-amino-salicylic acid Pentasa, mesalazine or asacole), as well as an immunomodulatory drug such as azathioprine (maximum one tablet/d) age: 18≤ 30<BMI ≥18/5

Exclusion criteria:

Change in the type and dosage of the drug during the past month The onset of some diseases such as : autoimmune diseases, cancer, inflammatory and infectious diseases) Pregnancy or lactation in women or the use of contraceptives The use of multi-vitamin - Mineral supplements, omega-3, polyphenols and antioxidants during one previous month The use of cholesterol lowering drugs (statins), NSAIDs, aspirin and diclofenac, antihistamines, anticoagulants, anti-TNF drugs, barbiturates, corticosteroids) during one previous month

Age

From **18 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

The Permuted Block randomization method will be used with Six-block blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to concealment in the randomization, unique codes will be used on the drug boxes, the code being generated by the software.

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, Shahid Hemmat Highway

City

tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.688

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

percentage of patients in clinical remission at the end of treatment, defined as SCCAI score

Timepoint

at baseline and end of study

Method of measurement

[Simple Clinical Colitis Activity Index] Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

at first and end of study

Method of measurement

IBDQ- 9 questionnaire

2

Description
Interleukin 17
Timepoint
at baseline and end of study
Method of measurement
ELISA kit

3

Description
Interleukin 10
Timepoint
at baseline and end of study
Method of measurement
ELISA kit

4

Description
PGC1-α gene expression
Timepoint
at baseline and end of study
Method of measurement
Real Time RT-PCR

5

Description
Sirt1 gene expression
Timepoint
at baseline and end of study
Method of measurement
Real Time RT-PCR

Intervention groups

1

Description
Intervention group: cap selenium 200 microgram 1/d
Category
Treatment - Drugs

2

Description
Control group: Rice flour Cap 1/d
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Maryam Khazdouz
Street address
Satarkhan St.
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6651 5001
Email
hrmc@iums.ac.ir

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, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
ivco@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Farzad Shidfar
Position
Professor of Nutrition
Latest degree

Ph.D.

Other areas of specialty/work
Nutrition

Street address
Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2503

Email
shidfar.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Professor of nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Shahid Hemmat highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8862 2755

Email
shidfar.f@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8862 2755

Email
shidfar.f@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The primary outcome is the capable to share at the end of the study

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Researchers working in academic institutes

Under which criteria data/document could be used
By requesting the correspond, there will be the possibility of using the data

From where data/document is obtainable
Professor Farzad Shidfar School of Public Health Iran University of Medical Science Hemmat, and Chamran Highways crossroad Tehran Iran. Tel: +98 21 86704743 Cell: +98 9123082922 Fax: +98 21 88622707 Email: shidfar.f@iums.ac.ir Additional email: farzadShidfar@yahoo.com

What processes are involved for a request to access data/document
When, an email sent to the correspond author, the data will usually be sent within 5 to 10 business days

Comments