# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 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**
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**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**
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Tehran
**Postal code**
1445613131
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Seyed Kazem Malakouti
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Iran University of Medical Sciences, Shahid Hemmat Highway
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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

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## Person responsible for scientific inquiries

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Professor of nutrition

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**Other areas of specialty/work**
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## Person responsible for updating data

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Professor

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## 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**