

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 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: $18 \leq$ years who have a confirmed endoscopic and histologic diagnosis of UC and active mild-to-moderate UC, $30 < \text{BMI} \leq 35$ 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 in 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 jejunum 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: $18 \leq 30 < \text{BMI} \geq 18/5$

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.

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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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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

Contact

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Person responsible for updating data

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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

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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