

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of soybean intake on disease severity, quality of life and hematologic factors of patients with ulcerative colitis

#### Protocol summary

##### Study aim

The effect of soybean consumption on disease severity, quality of life and hematologic factors in patients with ulcerative colitis

##### Design

A Randomized, controlled, parallel-group clinical trial on 40 patients with UC

##### Settings and conduct

Patients with UC will be recruited from Shariati and Imam Khomeini hospitals, Tehran, Iran. Then, patients will be assigned to intervention (soybean and routine treatment) and control (routine treatment) groups. Anthropometric measures and hematologic factors, disease severity, quality of life, disability caused by the disease will be assessed at the baseline and end of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate UC. Individuals who are smokers, those consuming alcohol, taking multivitamin-minerals, are pregnant or lactating or decided to get pregnant during the next three months, those who have infection over the past three months will not be included. We also will not include individuals with other pathologic conditions affecting the intestine, including cancer and infectious diseases. If a participant gets pregnant during the study, consume alcohol and/or use tobacco, multivitamin-mineral, he or she will be excluded. Any changes in medications throughout the study will also result in the exclusion.

##### Intervention groups

Patients in the intervention group will be receive 30 g/day soybean along with routine treatments. Participants in the control group will be receive only routine treatments.

##### Main outcome variables

Disease severity, quality of life, hematologic factors

#### General information

##### Reason for update

Sampling has been delayed due to covid-19

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191113045432N1**

Registration date: **2020-01-24, 1398/11/04**

Registration timing: **prospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **1**

##### Registration date

2020-01-24, 1398/11/04

##### Registrant information

##### Name

Sina Naghshi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 5975

##### Email address

naghshi\_sina@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-03-21, 1400/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of soybean intake on disease severity, quality of life and hematologic factors of patients with ulcerative

colitis

## Public title

The effect of soybean intake on disease severity, quality of life and hematologic factors of patients with ulcerative colitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with colitis ulcerative with moderate severity

### Exclusion criteria:

Alteration in type of drugs used for treatment of IBD within last 3 months Having other gut diseases such as related cancers and infections Pregnancy and lactation Admitting in hospital during last 3 months History of gut infections during last 3 months Using multivitamin/mineral supplements during last month

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will be stratified based on age (20 to 40 and 40 to 60 years), gender (male/female), body mass index (18.5 to 24.9 and 25 to 35), and type of medicines (anti-inflammatory and immunosuppressant) into dual blocks, and will be randomly allocated to the intervention or control groups. Random allocation will be done by lottery by a person who is unaware about the aim of our study.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Flat. 6, Office Building of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

## City

Tehran

## Province

Tehran

## Postal code

1417933331

## Approval date

2019-08-23, 1398/06/01

## Ethics committee reference number

IR.TUMS.VCR.REC.1398.506

## Health conditions studied

### 1

#### Description of health condition studied

colitis ulcerative

#### ICD-10 code

K51.9

#### ICD-10 code description

Ulcerative colitis, unspecified

## Primary outcomes

### 1

#### Description

Disease severity for colitis ulcerative

#### Timepoint

At the baseline and end of intervention

#### Method of measurement

Mayo-score questionnaire for colitis ulcerative

### 2

#### Description

Quality of life

#### Timepoint

At the baseline and end of intervention

#### Method of measurement

Questionnaire

### 3

#### Description

CBC

#### Timepoint

At the baseline and end of intervention

#### Method of measurement

Cell counter device

### 4

#### Description

ESR

#### Timepoint

At the baseline and end of intervention

#### Method of measurement

Wintergreen

**5**

**Description**

Disability caused by the disease

**Timepoint**

At the baseline and end of intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: daily intake of 30 g soybean produced by sobhan company along with routine treatment for colitis ulcerative patients

**Category**

Treatment - Other

**2**

**Description**

Control group: routine treatment for patients with colitis ulcerative

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Khomeini hospital

**Full name of responsible person**

Dr. Amirali Sohrabpour

**Street address**

Emam Khomeini hospital, Dr. Gharib Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 3007

**Fax**

**Email**

lmamhospital@tums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

shariati hospital

**Full name of responsible person**

Dr. Amirali Sohrabpour

**Street address**

Shariati hospital, Kargar Shomali Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Phone**

+98 21 8490 1000

**Email**

shariatihosp@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Leila Azadbakht

**Street address**

addressNo. 44, Hojatdost Ave, Naderi Ave, Keshavarz Blvd, Tehran city

**City**

Tehran

**Province**

Tehran

**Postal code**

1416643931

**Phone**

+98 21 8895 5742

**Email**

Info\_snsd@tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Sina Naghshi

**Position**

Master student of clinical nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

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**Email**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sina Naghshi

**Position**

Master student of clinical nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Email**

naghshi\_sina@yahoo.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sina Naghshi

**Position**

Master student of clinical nutrition

**Latest degree**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The study protocol will be written and published in the form of an article. Clinical report of our study will be published after finishing data gathering

**When the data will become available and for how long**

3 months after end of study

**To whom data/document is available**

The study findings will be made available to the general public

**Under which criteria data/document could be used**

For use in clinic or written a review article. For original studies, it will be permitted if they acknowledge our study personnel

**From where data/document is obtainable**

Using Email, by author who are responsible for updating data

**What processes are involved for a request to access data/document**

After receiving application by the author who are responsible for updating data and following consultation with scientific consultant, data will be provided

**Comments**