

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

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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

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Tehran

Postal code

1416643931

Phone

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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

No. 44, Hojatdost Ave, Naderi Ave, Keshavarz Blvd,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Email

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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