Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 colitits 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
Imamhospital@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.
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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
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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
No. 44, Hojatdost Ave, Naderi Ave, Keshavarz Blvd, Tehran city
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Person responsible for updating data

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Email
naghshi_sina@yahoo.com

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