Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effects of soy milk consumption on microbiota, inflammatory markers, quality of life, symptoms and disease severity in patients with colitits ulcerative

Protocol summary

Study aim
The effect of soy milk consumption on inflammatory biomarkers, gut microbiota, disease severity and symptoms in patients with ulcerative colitis (UC)

Design
Randomized controlled clinical trial with a parallel group design on 30 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 (soy milk and routine treatment) or control (routine treatment) groups. Anthropometric measures and biochemical factors will be assessed at the baseline and end of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria Patients with UC with moderate severity BMI between 18.5 and 30 Not-inclusion 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 Antibiotic use during last month Consumption of probiotic products during last month Admitting in hospital during last 3 months History of gut infections during last 3 months

Intervention groups
Patients in the intervention group will receive 200 mL/day soy milk along with routine treatments. Participants in the control group will receive only routine treatments.

Main outcome variables
Gut microbiota community; inflammatory biomarkers; fecal lactoferrin; fecal calprotectin; disease severity; disease symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181205041859N1**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-27, 1397/11/07**
Update count: **0**

Registration date
2019-01-27, 1397/11/07

Registrant information
Name
Omid Sadeghi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8898 4837
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omidsadeghi69@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-05, 1397/10/15

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of soy milk consumption on microbiota, inflammatory markers, quality of life, symptoms and

disease severity in patients with colitits ulcerative

Public title
The effects of soy milk consumption on gut microbium community, inflammatory markers, quality of life, symptoms and disease severity in patients with colitits ulcerative

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with colitits ulcerative with moderate severity body mass index between 18.5 and 30

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 Antibiotic use during last month Consumption of probiotic products during last month 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
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

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 30), 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
2018-10-07, 1397/07/15

Ethics committee reference number
IR.TUMS.VCR.REC.1397.445

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
gut microbiota community

Timepoint
at the baseline and end of intervention

Method of measurement
real-time PCR method

2

Description
fecal calpotectin

Timepoint
at the baseline and end of intervention

Method of measurement
ELISA

3

Description
fecal lactoferrin

Timepoint
at the baseline and end of intervention

Method of measurement
ELISA

Secondary outcomes

1

Description
serum hs-CRP levels

Timepoint

at the baseline and end of intervention

Method of measurement

ELISA

2

Description

disease severity for colitis ulcerative

Timepoint

at the baseline and end of intervention

Method of measurement

mayo-score questionnaire for colitis ulcerative

3

Description

disease symptoms such as diarrhea, presence of blood in stool and stomachache

Timepoint

at the baseline and end of trial

Method of measurement

questionnaire

4

Description

serum TNF-a levels

Timepoint

at the baseline and end of trial

Method of measurement

ELISA

5

Description

serum IL-1B levels

Timepoint

at the baseline and end of trial

Method of measurement

ELISA

6

Description

patients quality of life

Timepoint

at the baseline and end of trial

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: daily intake of 200 ml soy milk produced by mandasoy 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

Shariati hospital

Full name of responsible person

Dr. Alireza Sima

Street address

Shariati hospital, Kargar Shomali Ave.

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

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shariatihosp@tums.ac.ir

2

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Dr. Alireza Sima

Street address

Emam Khomeini hospital, Dr. Gharib Ave.

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Imamhospital@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

No. 44, Hojatdost Ave, Naderi Ave, Keshavarz Blvd, Tehran city

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Tehran
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1416643931
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+98 21 8895 5742
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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
Omid Sadeghi
Position
Ph.D student of nutrition
Latest degree
Master
Other areas of specialty/work
Nutrition
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No. 44, Hojatdost Ave, Naderi Ave, Keshavarz Blvd, Tehran city
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Latest degree
Master
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omidsadeghi69@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