

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

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

Phone

+98 21 8898 4837

Email address

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

2

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.

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2

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

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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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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
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Position
Ph.D student of nutrition
Latest degree
Master
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Person responsible for updating data

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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