

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effects of probiotic yogurt ingestion on inflammation parameters, micro flora and intestinal permeability in patients with inflammatory bowel disease

#### Protocol summary

##### Summary

Objective: to evaluate the effects of pro-biotic yogurt ingestion on inflammation parameters, micro flora and intestinal permeability in patients with inflammatory bowel disease. Study design: double blind randomized placebo controlled trial. Study population: 210 patients with inflammatory bowel disease. Inclusion criteria: ulcerative colitis or crohn's disease patients; no history of using pro-biotic and pro-biotic supplements, antioxidant vitamin and omega-3 fatty acids supplements, using antibiotic drugs within last 3 months. Exclusion criteria: not interested to continue the study and need for change drug's doses or types during the study. Intervention: 250 grams of pro-biotic yogurt will be given daily to intervention group and 250 grams of non-pro-biotic yogurt daily to control group for two months. Primary study outcomes: IL-10, CRP, IL-6, IL-1 beta, TNF-alpha-intestinal permeability.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105106431N1**

Registration date: **2012-06-05, 1391/03/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-06-05, 1391/03/16

##### Registrant information

###### Name

Mahdi Shadnoush

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

shadnoush@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2012-05-05, 1391/02/16

##### Expected recruitment end date

2012-11-05, 1391/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of probiotic yogurt ingestion on inflammation parameters, micro flora and intestinal permeability in patients with inflammatory bowel disease

##### Public title

Effects of probiotic yogurt ingestion on inflammation and intestinal function in patients with inflammatory bowel disease

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- Ulcerative colitis or crohn's disease patients; 2- No history of using probiotic and prebiotic supplements within last 3 months; 3- No history of using antioxidant vitamin supplements within last 3 months; 4- No history of using omega-3 fatty acids supplements

within last 3 months; 5- No history of using antibiotic drugs within last 3 months; 6- No history of other inflammatory diseases like rheumatoid arthritis and infectious disease; 7- No history of other gastrointestinal disease; 8- Body mass index(BMI) between 18.5 and 30; 9- No pregnancy and lactating stage in women; 10- Interested in participation and complete consent form. Exclusion criteria: 1-Not interested to continue the study; 2-Need for change drug's doses or types during the study.

#### 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: **210**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences

##### Street address

Velenjak

##### City

Tehran

##### Postal code

#### Approval date

2011-02-27, 1389/12/08

#### Ethics committee reference number

89-01-100-7384-5091

## Health conditions studied

### 1

#### Description of health condition studied

Inflammatory bowel disease

#### ICD-10 code

K51

#### ICD-10 code description

Ulcerative colitis

### 2

#### Description of health condition studied

Inflammatory bowel disease

#### ICD-10 code

K50

#### ICD-10 code description

Crohn's disease

## Primary outcomes

### 1

#### Description

IL-1beta

#### Timepoint

At baseline and at the end

#### Method of measurement

ELISA commercial kits

### 2

#### Description

TNF-alpha

#### Timepoint

At baseline and at the end

#### Method of measurement

ELISA commercial kits

### 3

#### Description

intestinal microflora

#### Timepoint

At baseline and at the end

#### Method of measurement

Real-time PCR

### 4

#### Description

Intestinal permability

#### Timepoint

At baseline and at the end

#### Method of measurement

HPLC

### 5

#### Description

IL-6

#### Timepoint

at baseline and at the end

#### Method of measurement

ELISA commercial kits

### 6

#### Description

CRP

**Timepoint**

At baseline and at the end

**Method of measurement**

ELISA commercial kits

**7****Description**

IL-10

**Timepoint**

At baseline and at the end

**Method of measurement**

ELISA commercial kits

**Secondary outcomes****1****Description**

dietary intake of different fatty acids

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**2****Description**

dietary intake of energy

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**3****Description**

dietary intake of macronutrient

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**4****Description**

dietary intake of cholesterol

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**5****Description**

dietary intake of antioxidant vitamins

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**6****Description**

dietary intake of fiber

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**7****Description**

dietary intake of calcium

**Timepoint**

At baseline and at the end

**Method of measurement**

Nutritionist IV, a software program

**Intervention groups****1****Description**

Control group: non-probiotic yogurt ingestion for 8 weeks (250 grams daily)

**Category**

Treatment - Other

**2****Description**

Intervention group: probiotic yogurt ingestion for 8 weeks (250 grams daily)

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imamhosein Hospital

**Full name of responsible person****Street address****City**

Tehran

**2****Recruitment center****Name of recruitment center**

Gastroenterology and liver research center

**Full name of responsible person****Street address****City**

Tehran

**3****Recruitment center****Name of recruitment center**

Azar Clinic

**Full name of responsible person**  
**Street address**  
**City**  
Tehran

**4**

**Recruitment center**  
**Name of recruitment center**  
Taleghani hospital  
**Full name of responsible person**  
**Street address**  
**City**  
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## Sponsors / Funding sources

**1**

**Sponsor**  
**Name of organization / entity**  
Vice Chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mohammad Rahmati Roodsari  
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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**  
Vice Chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

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## Sharing plan

Deidentified Individual Participant Data Set (IPD)

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*