

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Evaluation of the effect of ginger supplementation on clinical outcomes, serum levels of some inflammatory markers(TNF- $\alpha$ , hs-CRP) , TAC and expression of mir-21 in patients with active ulcerative colitis

#### Protocol summary

##### Study aim

Determine the effect of ginger supplement on clinical status, serum levels of some inflammatory markers (TNF- $\alpha$ , hs-CRP), total antioxidant capacity (TAC) and expression of mir-21 in patients with active ulcerative colitis

##### Design

A double-blinded randomized controlled trial with two parallel groups

##### Settings and conduct

The clinical trial will be held at IBD clinic in the hospital, Ahvaz Jundishapur University of Medical Science, to assess the efficacy of daily 3 g ginger supplementation adjunctive in active ulcerative colitis patients.

##### Participants/Inclusion and exclusion criteria

Active ulcerative colitis

##### Intervention groups

Ginger supplementation

##### Main outcome variables

Clinical score Mir-21 TNF- $\alpha$  HsCRP TAC

#### General information

##### Reason for update

##### Acronym

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##### IRCT registration information

IRCT registration number: **IRCT20190129042552N1**

Registration date: **2019-06-21, 1398/03/31**

Registration timing: **prospective**

Last update: **2019-06-21, 1398/03/31**

Update count: **0**

##### Registration date

2019-06-21, 1398/03/31

##### Registrant information

##### Name

Forough Shayesteh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3376 5113

##### Email address

forough\_shayesteh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-22, 1398/04/01

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of ginger supplementation on clinical outcomes, serum levels of some inflammatory markers(TNF- $\alpha$ , hs-CRP) , TAC and expression of mir-21 in patients with active ulcerative colitis

##### Public title

Evaluation of the effect of ginger supplementation on clinical outcomes, serum levels of some inflammatory markers, TAC and expression of mir-21 in patients with active ulcerative colitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Moderate to severe active ulcerative colitis patients  
Absence of fulminant colitis Male and female aged 18 to 50 years Body mass index 18/5 - 30 Lack of other digestive disorders and uncontrolled disease Lack of sensitivity to ginger

**Exclusion criteria:**

Use of anti TNF- $\alpha$  Pregnancy Menopause Use of anti-coagulants, anti-diabetic and anti-blood pressure medication

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization in this study will be done by simple method. The unit of randomization is individual. Using a random number table, a number is considered for each patient, respectively. Odd or even numbers will be allocated to the A or B group. To achieve allocation concealment, the bottles will be sealed and we will be assured from the similarity of appearance and their weight. The randomization process will be performed by an individual other than the investigators to reduce the probable bias.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Ginger and placebo capsules (in identical appearance container) are encoded by someone other than researcher

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

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**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz university of medical sciences

**Street address**

Golestan Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

1579461357

**Approval date**

2019-02-23, 1397/12/04

**Ethics committee reference number**

ir.ajums.rec.1397.893

**Health conditions studied**

**1**

**Description of health condition studied**

Ulcerative colitis

**ICD-10 code**

K51

**ICD-10 code description**

Ulcerative colitis

**Primary outcomes**

**1**

**Description**

Clinical score

**Timepoint**

Before and after intervention

**Method of measurement**

Partial mayo score

**2**

**Description**

Serum level of mir-21

**Timepoint**

Before and after intervention

**Method of measurement**

PCR

**3**

**Description**

Serum level of TNF- $\alpha$

**Timepoint**

Before and after intervention

**Method of measurement**

Elisa kit

**Secondary outcomes**

**1**

**Description**

Serum level of hs-CRP

**Timepoint**

Before and after intervention

**Method of measurement**

Elisa kit

**2**

**Description**

Total antioxidant capacity  
**Timepoint**  
Before and after intervention  
**Method of measurement**  
Elisa kit

## Intervention groups

1

**Description**  
Intervention group: ginger supplementation 3 grams per day for 3 months  
**Category**  
Other

2

**Description**  
Control group: placebo supplementation 3 grams daily for 3 months  
**Category**  
Other

## Recruitment centers

1

**Recruitment center**  
**Name of recruitment center**  
Imam khomeini hospital  
**Full name of responsible person**  
Forough shayesteh  
**Street address**  
Golestan Blvd  
**City**  
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15794-61357  
**Phone**  
+98 61 3333 3477  
**Email**  
Forough\_shayesteh@yahoo.com

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
---  
**Street address**  
Golestan Blvd  
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Khouzestan  
**Postal code**

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**Email**  
behsan@ajums.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz 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**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Forough shayesteh  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
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## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Fatemeh haidari  
**Position**  
Associated professor  
**Latest degree**  
Ph.D.

**Other areas of specialty/work**

Nutrition

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haidari58@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Forough shayesteh

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Golestan blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

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**Phone**

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**Email**

Forough\_shayesteh@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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available