Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of ginger supplementation on clinical outcomes, serum levels of some inflammatory markers(TNF-α, 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-α, 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-α HsCRP TAC

General information

Reason for update

Acronym

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-α, 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 sever 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-α 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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee 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-a

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

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

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Fatemeh haidari

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Person responsible for updating data

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Name of organization / entity
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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
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