

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effects of Zingiber officinale on quality of life, disease activity index, and Serum levels of some inflammatory factors and oxidative stress in patients with ulcerative colitis

Protocol summary

Summary

Investigation of the effects of Zingiber officinale on quality of life, disease activity index, and Serum levels of some inflammatory factors and oxidative stress in patients with ulcerative colitis randomized double blind placebo controlled trial Inclusion criteria: cases with ulcerative colitis; Disease duration less than two years; active mild to moderate disease severity; no use of alcohol; Insensitivity to ginger; no disease else; no use of any dietary supplements; Anticoagulant drugs and Non-steroidal anti-inflammatory drugs (NSAIDs) during the last month; BMI over than 18.5 and less than 30; age equal and more than 18 years; tendency to participate in this research; no change in type and dose of drug usage during last month.; not pregnancy, not lactation and no use of oral contraceptive drugs in women exclusion criteria: Relapse of disease leading to patient hospitalization; Ginger sensitivity; the patient Unwillingness to continue participation in this research. number of cases in each group: 25 and method of sampling: Convenience Sampling summary of implementation of plan: If patients want to participate in this study, by prior arrangement, they will come to gastrointestinal center and 12-14 h fasting blood samples will be collected, anthropometric measurements and dietary Assessment and necessary information will be gathered. then they randomly will be divided into one of two consumer groups of ginger or placebo capsules. capsules for usage during first 6 weeks will be delivered to them. The duration of the intervention takes 12 weeks and they must consume ginger or placebo capsules 4 times per day with some water and with their meals. in the middle and at the end of 12 weeks they will come to gastrointestinal center again and 12-14 h fasting blood samples will be collected, anthropometric measurements and dietary Assessment and necessary information will be gathered. also capsules for second 6 weeks will be

delivered at second meeting to them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703164010N17**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 0824

Email address

hekmat@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research
Institute

Expected recruitment start date

2017-04-20, 1396/01/31

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effects of Zingiber officinale on quality of life, disease activity index, and Serum levels of some inflammatory factors and oxidative stress in patients with ulcerative colitis

Public title
Investigation of the effect of ginger on ulcerative colitis treatment

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: cases with ulcerative colitis; Disease duration less than two years; active mild to moderate disease severity; no use of alcohol; Insensitivity to ginger; no disease else; no use of any dietary supplements; Anticoagulant drugs and Non-steroidal anti-inflammatory drugs (NSAIDs) during the last month; BMI over than 18.5 and less than 30; age equal and more than 18 years; tendency to participate in this research; no change in type and dose of drug usage during last month; not pregnancy, not lactation and no use of oral contraceptive drugs in women exclusion criteria: Relapse of disease leading to patient hospitalization; Ginger sensitivity; the patient Unwillingness to continue participation in this research

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Ethics committee of National Nutrition and Food Technology Research Institute

Street address
National Nutrition and Food Technology Research Institute, Faculty of Nutrition Sciences and Food Technology, Shahid Beheshti University of Medical Sciences, West Arghavan Street, Farahzadi Boulevard, Sanaat Square, Tehran

City
Tehran

Postal code

Approval date
2017-03-06, 1395/12/16

Ethics committee reference number
IR.SBMU.NNFTRI.1395.109

Health conditions studied

1

Description of health condition studied
Ulcerative colitis

ICD-10 code
K51.9

ICD-10 code description
Ulcerative colitis, unspecified

Primary outcomes

1

Description
serum MDA

Timepoint
at the first of research. 6thweek. end of research(12th week)

Method of measurement
Elisa

2

Description
Serum hs-CRP

Timepoint
at the first of research. 6thweek. end of research(12th week)

Method of measurement
Elisa

3

Description
TNF- α

Timepoint
at the first of research. 6thweek. end of research(12th week)

Method of measurement
Elisa

4

Description

TAC

Timepoint

at the first of research. 6thweek. end of research(12th week)

Method of measurement

Elisa

5

Description

Life Quality

Timepoint

at the first of research. 6thweek. end of research(12th week)

Method of measurement

Questionnaire

6

Description

Disease Activity Index

Timepoint

at the first of research. 6th week. end of research(12th week)

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Weight

Timepoint

at the first of research. 6thweek. end of research(12th week)

Method of measurement

scale

2

Description

BMI

Timepoint

at the first of research. 6thweek. end of research(12th week)

Method of measurement

Calculation

Intervention groups

1

Description

the supplement of powdered ginger during12 weeks.4(0.5gr) capsules daily

Category

Treatment - Other

2

Description

the capsules of placebo (starch) during12 weeks. number4(0.5 gr) capsules daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of Dr.Iraj Maleki

Full name of responsible person

Dr.Iraj Maleki

Street address

Second floor of Sina Department,GHaran street,Sari,Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Morteza Abdollahi

Street address

Department of National Nutrition and Food Technology Research Institute, Faculty of Nutrition Science, Shahid Beheshti University of Medical Sciences, West Arghavan Street, Farahzadi Boulevard,Sanaat Square, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

National Nutrition and Food Technology Research Institute

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

Contact

Name of organization / entity

Faculty of Nutrition Sciences and Food Technology,
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Position

First Executer

Other areas of specialty/work**Street address**

Clinical Nutrition Department, Faculty of Nutrition
Sciences and Food Technology, Shahid Beheshti
University of Medical Sciences, West Arghavan Street,
Farahzadi Boulevard, Sanaat Square, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21522357483

Fax**Email**

A_hekmat2000@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

(Department) National Nutrition and Food Technology
Research Institute, Faculty of Nutrition Science

Full name of responsible person

Azita Hekmetdoost

Position

Nutritionist

Other areas of specialty/work**Street address**

Clinical Nutrition Department, Faculty of Nutrition
Sciences and Food Technology, Shahid Beheshti
University of Medical Sciences, West Arghavan Street,
Farahzadi Boulevard, Sanaat Square, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 2235 7483

Fax**Email**

A_hekmat2000@yahoo.com

Web page address

Person responsible for updating data

Contact

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