

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effects of oral supplementation ellagic acid on anti-oxidant status, inflammatory markers, and quality of life in a patient with irritable bowel syndrome: randomized double-blind clinical trial

Protocol summary

Study aim

The determination of inflammatory factors including Interleukin 6 (IL-6), C-reactive protein (CRP), total antioxidant capacity (TAC), malondialdehyde concentration and quality of life score

Design

In this study, 44 patients with irritable bowel syndrome who are eligible for inclusion in the study and referred to the Gastroenterology Department of Velayat Hospital of Qazvin University of Medical Sciences are selected. Participants are randomly assigned to two intervention and control groups and each participant is assigned a code.

Settings and conduct

This study is a randomized double-blind clinical trial. People with irritable bowel syndrome referring to the Department of the Gastroenterology Department of Velayat Hospital of Qazvin University of Medical Sciences, are referred by a gastroenterologist, consultant to this study. Then, 44 patients were selected and randomly divided into intervention and control groups. In this study, the investigator and the patient will be blinded to drugs and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients who are 19-60 years old diagnosed with Irritable Bowel Syndrome according to ROME III criteria; Signed consent by the patient. Exclusion criteria: The patients who have celiac disease; any other diseases of the gastrointestinal tract; abdominal surgery; chronic disease such as diabetes, cardiovascular, hepatic, kidney and severe infection; pregnancy; breastfeeding; alcohol consumption; Use of dietary supplements.

Intervention groups

Intervention group: the group receiving ellagic acid (200mg daily) Control group: placebo group

Main outcome variables

Inflammatory factors, oxidative stress indices and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N11**

Registration date: **2019-01-12, 1397/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-01, 1398/07/09**

Update count: **1**

Registration date

2019-01-12, 1397/10/22

Registrant information

Name

Hossein Khadem Haghghian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

Email address

khadem.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of oral supplementation ellagic acid on anti-oxidant status, inflammatory markers, and quality of life in a patient with irritable bowel syndrome: randomized double-blind clinical trial

Public title

Ellagic acid supplementation in patient with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women with irritable bowel syndrome

Exclusion criteria:

Patients with gastrointestinal problems such as celiac disease and infection of the gastrointestinal tract

Age

From **19 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

It will be done with simple random method using the lottery. For each patient, a number or code is provided, then the numbers will be written on pieces of paper. The pieces of paper are placed in a container and well stirred, and the sample is selected according to the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients of both sexes are randomly divided into two groups, intervention and control groups, using a randomized distribution method. In this study, the patient and researcher are blinded to medicine and placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University Of Medical Sciences

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.QUMS.REC.1397.201

Health conditions studied**1****Description of health condition studied**

Irritable bowel syndrome

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhea

Primary outcomes**1****Description**

Inflammatory factors

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

2**Description**

Antioxidant indices

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

3**Description**

Quality of life

Timepoint

Before intervention and after intervention

Method of measurement

Irritable Bowel Syndrome Quality of Life Questionnaire.

4

Description

Sleep quality

Timepoint

Before intervention and after intervention

Method of measurement

Petersburg's sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ellagic acid, a capsule 200 mg per daily for two months, Manufacturer: Supplement Spot

Category

Treatment - Drugs

2

Description

Control group: A daily placebo capsule containing wheat flour for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Hossein Khadem Haghighian

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Peimani

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

59811 -34197

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

By contacting the email address of a person responsible for general inquiries

When the data will become available and for how long

After completing the study and analyzing the data

To whom data/document is available

All researchers

Under which criteria data/document could be used

There is no objection to the use of data provided the source of the resource.

From where data/document is obtainable

By contacting the email address of a person responsible for general inquiries

What processes are involved for a request to access data/document

Six months after the study

Comments