

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the effectiveness of olive oil rich in polyphenols and ordinary olive oil in the treatment of patients with chronic constipation

#### Protocol summary

##### Study aim

Comparison of the effectiveness of profenol olive oil and regular on chronic constipation

##### Design

All eligible individuals will be divided into intervention and control groups using block randomization method with 4 and 6 block sizes. To generate a randomization list from the online randomization service Sealed Envelope Ltd. 2019 was used (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>).

##### Settings and conduct

The present study is a clinical trial study. In this study, 150 people with a diagnosis of constipation according to the Rome III criterion who referred to the Caspian Clinic will be randomly admitted to the study

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a criterion for diagnosing constipation based on the Rome III criterion, people over 18 years Conditions of absence: Organic constipation, hypothyroidism, false intestinal obstruction, cystic fibrosis, neurological abnormalities, intestinal obstruction, opium use, use of laxatives

##### Intervention groups

One group will be given olive oil rich in polyphenols and the other group will be given regular olive oil. The amount of olive oil given will be 20 ml / liter per day (about two tablespoons) for 4 weeks.

##### Main outcome variables

Elimination chronic constipation

#### General information

##### Reason for update

In the implementation method, the amount of olive oil given to people with constipation is two tablespoons, which is equivalent to 20 ml, but at the time of registration, 4 ml was incorrectly mentioned.

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20080901001155N33**

Registration date: **2021-03-01, 1399/12/11**

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

Last update: **2021-05-07, 1400/02/17**

Update count: **1**

#### Registration date

2021-03-01, 1399/12/11

#### Registrant information

##### Name

Farahnaz Joukar

##### Name of organization / entity

Guilan University of Medical Sciences,  
Gastrointestinal and liver disease Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1553 5116

##### Email address

info@glrc.org

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-02-17, 1399/11/29

#### Expected recruitment end date

2021-08-19, 1400/05/28

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effectiveness of olive oil rich in polyphenols and ordinary olive oil in the treatment of

patients with chronic constipation

### Public title

the effectiveness of olive oil rich in polyphenols and ordinary olive oil in the treatment of patients with chronic constipation

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having a constipation diagnosis based on the Rome III criterion People over 18 years old

#### Exclusion criteria:

Existence of organic constipation Hypothyroidism False intestinal obstruction Cystic fibrosis Neurological anomalies Ileus Opium consumption Taking laxatives such as MOM

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: **150**

### Randomization (investigator's opinion)

Randomized

### Randomization description

All eligible individuals will be divided into intervention and control groups using block randomization method with 4 and 6 block sizes. To generate a randomization list from the online randomization service Sealed Envelope Ltd. 2019 was used (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>).

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Participants and health care personnel will not be informed of the type of group therapy received in a double-blind manner. To do this, ordinary olive oil is quite similar to polyphenol olive oil will be ordered and provided to these people.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

### Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

### Street address

Research and Technology Deputy ,Shaheed Beheshti street,Gaz square,Rasht

### City

Rasht

### Province

Guilan

### Postal code

41448956655

### Approval date

2021-02-17, 1399/11/29

### Ethics committee reference number

IR.GUMS.REC.1399.600

## Health conditions studied

### 1

#### Description of health condition studied

Chronic constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

## Primary outcomes

### 1

#### Description

Elimination chronic constipation

#### Timepoint

The questionnaire will be asked at the beginning of the patient's arrival and at the end of the fourth week

#### Method of measurement

The Rome III questionnaire

## Secondary outcomes

### 1

#### Description

Stool deformity

#### Timepoint

At the end of each week, the patient will be asked by telephone

#### Method of measurement

Based on the Bristol Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Olive oil rich in polyphenols,The amount of olive oil given will be 20 ml per day (about two tablespoons) for 4 weeks.

#### Category

Treatment - Other

## 2

### Description

Control group: Ordinary olive oil, The amount of olive oil given will be 20 ml per day (about two tablespoons) for 4 weeks.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Caspian Digestive Disease Research Center

##### Full name of responsible person

Dr.Fariborz Mansour ghanaei

##### Street address

Gastrointestinal and Liver Diseases Research Center,  
Razi Hospita, Sardar Jangal Ave, Rasht, Iran

##### City

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##### Province

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##### Postal code

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##### Phone

+98 13 3353 5116

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ghanaie@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Gastrointestinal and liver Disease Research Center

##### Full name of responsible person

Dr.Fariborz Mansour ghanaei

##### Street address

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Razi Hospita, Sardar Jangal Ave, Rasht, Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

Dr.Mohammad Hadi Bahadori

#### Street address

Vice Chancellor for Research, Shahid Sadati St,  
Namjoo St, Rasht

#### City

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#### Province

Guilan

#### Postal code

41448-95655

#### Phone

+98 13 3334 6489

#### Fax

+98 13 3333 3125

#### Email

bahadori@gums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rasht 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

Rasht University of Medical Sciences

##### Full name of responsible person

Dr.Fariborz Mansour-Ghanei

##### Position

Full Professor of Internal Medicine & Gastroenterology

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Specialist in gastrointestinal and liver diseases

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Razi Hospita, Sardar Jangal Ave, Rasht, Iran

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ghanaie@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences

**Full name of responsible person**  
Dr. Farahnaz Joukar

**Position**  
Deputy of Gastrointestinal and Liver Diseases  
Research Center

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Epidemiology

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farajov@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences

**Full name of responsible person**  
Mehrnaz Asgharnezhad

**Position**  
Master of Nursing

**Latest degree**  
Master

**Other areas of specialty/work**  
Nursery

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Gastrointestinal and Liver Diseases Research Center,  
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asgharnezhad98@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

Yes - There is 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

The main outcome of this study, which is chronic constipation, will be made available to the general public

### When the data will become available and for how long

One year after printing results

### To whom data/document is available

Researchers at relevant research centers, universities and related doctors

### Under which criteria data/document could be used

In this case, the decision has not yet been taken

### From where data/document is obtainable

Mehrnaz Asgharnezhad Gastrointestinal and Liver Diseases Research Center Guilan, Razi hospital, Rasht ,41448-955655,01333535116

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

At the outset, the applicant will email and complete his or her full introduction of the organization and the purpose of obtaining this data and will request the relevant documents or files. Subsequently, the data files will be made available to the applicant within the time period stated by the relevant investigator

### Comments