Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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
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Gastrointestinal and Liver Diseases Research Center, Razi Hospita, Sardar Jangal Ave, Rasht, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Specialist in gastrointestinal and liver diseases
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Person responsible for updating data

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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