Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of syrup containing extract of Fucus carica and Actinidia deliciosa in patients with constipation

Protocol summary

Study aim
The effect of fig fruit and kiwi extract on constipation.
Design
Clinical trial with control and parallel groups, single-blinded, randomized, in 2 phase, has been conducted on 70 patients. RAND function in Excel software has been used for randomization purposes.
Settings and conduct
The clinical trial has been conducted in 2 phase on 70 patients with constipation referring to gastroenterology clinic of Imam Khomeini Hospital. The study is single-blinded and only the subjects have been put blind.
Participants/Inclusion and exclusion criteria
Compliance with Constipation diagnostic criteria, the age range is 18-70 years. Signing the informed consent. Exclusion criteria: Pregnancy, lactation, the existence of underlying illnesses, allergy to fig and kiwi, consumption of Constipation improvement medicines.
Intervention groups
Intervention group: Oral prescription of a syrup containing extract of fig fruit and kiwi, made in Pharmacognosy laboratory of Tehran's University of Medical Science, administered on 35 Constipation patients, two times a day (morning-.evening), for a one-month period. Control group: Oral prescription of a Lactulose syrup administered on 35 Constipation patients, two times a day (morning-evening), for a one month period.
Main outcome variables
Constipation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160306026938N14**
Registration date: **2022-10-18, 1401/07/26**
Registration timing: **prospective**
Last update: **2022-10-18, 1401/07/26**
Update count: **1**
Registration date
2022-10-18, 1401/07/26

Registrant information
Name
Mahdi Vazirian
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-06, 1401/08/15
Expected recruitment end date
2023-01-20, 1401/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of syrup containing extract of Fucus carica and Actinidia deliciosa in patients with constipation

Public title
The effect of fig fruit and kiwi extract on constipation.
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Being afflicted with constipation Age range of 18-70 years old Signing the informed consent
Exclusion criteria:
Being afflicted with any underlying disease Pregnancy Being allergic to fig and kiwi. Lactation periode Consumption of medications for improvement of constipation

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 70 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 35 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 70.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only the participants were not informed about receiving either treatment/placebo capsules. Thus, the study is a single-blinded one. The subjects in this study were not either relatives or friends, thus they couldn't compare the impacts of receiving placebo/treatment. In addition, the appearance of the syrups and their containing package was exactly similar in both Intervention/control group and is not differentiated. All the study subjects received a good deal of information regarding the research plan and have been presented to them .After being randomized through the use of statistical software package, treatment/placebo has been provided for them.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethichs Committees of The Institute of Pharmaceutical Sciences- Tehran University Of Medica

Street address
16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219.

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2022-09-04, 1401/06/13

Ethics committee reference number
IR.TUMS.TIPS.REC.1401.045

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Constipation

Timepoint
After intervention

Method of measurement
Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms(0=no improvement; 10= complete improvement)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral prescription of a syrup containing extract of fig fruit and kiwi, made in Pharmacognosy laboratory of Tehran's University of Medical Science, administered on 35 Constipation patients, two times a day (morning-evening), for a one-month period.

Category

Treatment - Drugs

2

Description
Control group: Oral prescription of a Lactulose syrup administered on 35 Constipation patients, two times a day (morning-evening), for a one month period.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology clinics of Imam Khomeini hospital
Full name of responsible person
Dr. Mohammad Taher
Street address
Imam Khomeini Hospital, Keshavarz Blvd, Tehran, Iran
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1419733141
Phone
+98 21 6693 9009
Email
imamhospital@tums.ac.ir
Web page address
http://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Aliakbar Fotohi
Street address
Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz
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1417653761
Phone
+98 21 8163 3619
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rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mahdi Vazirian
Position
PhD of Pharmacognosy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Demographic specification of patients, would be published, except their names and address. Primary outcome of the patients would be published, too.

When the data will become available and for how long
Data would be available 6 months after publishing the results.

To whom data/document is available
.Data would be available for researchers in academic and scientific organisations.

Under which criteria data/document could be used
Any type of usage of data is allowable, except using for manufacturing a product.

From where data/document is obtainable
Sending an E. mail to mehdivazirian@gmail.com

What processes are involved for a request to access data/document
After receiving E. mail, data would be sent within a week.

Comments