

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

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

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

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Email

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

Street address

Pharmacognosy Lab., Second Floor, New building, Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6412 1223

Fax

Email

Vazirian_m@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

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Phone

+98 21 6412 1223

Fax

Email

Vazirian_m@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

Teacher Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacognosy Lab., Second Floor, New buliding,
Faculty of Pharmacy, In front of Oruji Alley, 16th A

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6412 1223

Fax

+98 21 6695 4706

Email

vazirian_m@tums.ac.ir

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