# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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 buliding, 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**
PhD of Pharmacognosy
**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 Azar

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**Postal code**
1417614411

**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**