# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Aug 2026

## The Comparison of the effects of traditional remedy of Foeniculum vulgare and Rosa Damascena on clinical symptoms of elderly patients with functional constipation

### Protocol summary

**Study aim**
Determination of the effect Traditional remedy of Foeniculum vulgare and Rosa domascena on Clinical Symptoms of Elderly Patients with Functional Constipation

**Design**
Patients were randomly assigned to either an intervention or a control group. included 30 people who were blocked randomly assigned to the each group.Intervention group,patients with functional constipation treated with combination of Rosa domascena and Foeniculum vulgare extract. The control group includes Patients who mix and consume of Poly Ethylene Glycol powder

**Settings and conduct**
This double blind study will perform on elderly patients with constipation on urban health service centers in Kerman city.Medicines are manufactured by a traditional pharmacist and packaged and coded in the same way.One who performs coding until the end of the intervention has no role in the study. Patients by someone who is unaware of how the drugs are coded,Until the end of the intervention, there was no role in the study. Patients are randomly assigned to one of the two groups studied, followed and followed up by a person who does not know how the medication is coded

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:Elderly patients over 60 years of age who are mentally alert and able to answer questions and have constipation based on the approved Rome IV criteria. Exclusion criteria: History of gastrointestinal obstructive diseases, psychiatric disorders, history of drug abuse, patient's unwillingness to continue the plan.

**Intervention groups**
Case group: 10 gr traditional remedy (5 gr Foeniculum vulgare and 5 gr Rosa domascena), two times a day
Control group: 10 gr PEG, two times a day

**Main outcome variables**
Constipation

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200108046056N1**
Registration date: **2020-02-25, 1398/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-25, 1398/12/06**
Update count: **0**

**Registration date**
2020-02-25, 1398/12/06

**Registrant information**

**Name**
Sedigheh khodabandeh Shahrki

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-02-20, 1398/12/01

**Expected recruitment end date**
2020-07-22, 1399/05/01

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Comparison of the effects of traditional remedy of Foeniculum vulgare and Rosa Damascena on clinical symptoms of elderly patients with functional constipation

**Public title**

Traditional remedy of Foeniculum vulgare and Rosa Damascena on clinical symptoms of elderly patients with constipation

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The elderly over 60 years of age mentally alert and able to answer questions constipation approved in accordance with Rome IV diagnostic criteria. informed consent. Having informed consent no history of gastrointestinal obstructive disorders. No history of gastrointestinal inflammatory diseases.

**Exclusion criteria:**

unwillingness to continue participation in the study at any time of the study. The occurrence of acute complications during the intervention. use of laxatives for constipation during the study. Reporting any signs suggesting an allergic reaction to Foeniculum vulgare and Rosa Damascena. Not taking regular medication

**Age**

From **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

60 people aged 60 years Community Health Centers who suffer from constipation each person has a proprietary code given by A statistic consultant is provided in blocks 4 and unaware of which code belongs to which group is placed in the envelope (with random allocation based on the referral of patients) and the subjects are randomly assigned to two groups of control and intervention. Questionnaires are completed before and after the intervention by a researcher who is unaware of the intervention and control group. Constipation is the main variable in this studyp also performs the usual treatment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double blind study. Medicines are manufactured by a traditional pharmacist and packaged and coded uniformly. The person doing the coding has no role in the study until the end of the intervention. Patients are randomly assigned to one of the two study groups by a person who has no knowledge of how the drugs are coded. Statistical analysis of the study is performed by a third person who is unaware of how the groups are coded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences and Health Services

**Street address**

Jahad Blvd. Ebn Sina Avenue, Kerman, Iran

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**Approval date**

2020-01-13, 1398/10/23

**Ethics committee reference number**

IR.KMU.REC.1398.470

## Health conditions studied

### 1

**Description of health condition studied**

constipation

**ICD-10 code**

K59.0

**ICD-10 code description**

Constipation

## Primary outcomes

### 1

**Description**

People with constipation who have 2 or more grade according to Rome 4 criteria

**Timepoint**

All of the above groups meet weekly on a weekly basis: initial visit and diagnosis before the intervention, one month after intervention and two month after the

intervention intervention

**Method of measurement**

Questionnaire based on the international diagnostic criteria of chronic constipation-ROMIV

## Secondary outcomes

### 1

**Description**

Quality Of Life

**Timepoint**

Before the intervention. one month after intervantion, two month after the interventionintervention

**Method of measurement**

Patient Assessment of Constipation Quality of Life Questionnaire

## Intervention groups

### 1

**Description**

Intervention group: Patients with chronic constipation treated with sachet of Roses Damascena and Foeniculum vulgare which was produced at the Kereman university of Medical Science, faculty of Persian medicine, as a sachet and dosed with the desired dosage . 10 grams of sachets (containing 5 grams of Foeniculum vulgare powder and 5 grams of Rosa domascena powder), two times a day, in the morning and evening before meals and mix with a glass of warm water.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: 10 gr sachet of PEG powder, two times a day, in the morning and evening before meal, with one glass of warm water

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Health Service Centers

**Full name of responsible person**

Sedighe Khodabandeh Shahraki

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## Sponsors / Funding sources

### 1

**Sponsor**

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**Full name of responsible person**

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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**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Sedigh Khodabandeh Shahrki

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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Traditional Medicine

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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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
Only, information about the outcome of the study will be published.

**When the data will become available and for how long**
The publication time after the publication of the results will be in a journal.

**To whom data/document is available**
Anyone who wants to have access to information after publishing in a journal.

**Under which criteria data/document could be used**
Analysis of data based on statistical software.

**From where data/document is obtainable**
Kerman University of Medical Sciences.After publication in a journal can go to the website of the journal. Refer to this email:s_khodabandeh@kmu.ac.ir

**What processes are involved for a request to access data/document**
After the publication of the study information in a journal, it can immediately access the information.

**Comments**