Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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+98 34 3132 5218

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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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Province

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Postal code

7619813159

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

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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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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