

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of *Descurainia sophia* (L.) seed Webb ex Prantl on the severity of functional constipation in Women 50-70 years old .

Protocol summary

Study aim

Providing a complementary medicine solution along with other treatments to reduce drug dependence and a safe, easy and acceptable solution for improvement and prevention in elderly patients with functional constipation

Design

Clinical trial with control group, with parallel groups, one blind, randomized

Settings and conduct

The researcher and analyst assistants are both blind. The site of the study is the Social Security Hospital Clinic. After the samples are selected, the questionnaire is filled in by the researcher's assistance. The training is given to each group by the researcher. The questionnaire is then re-filled up with the help of a researcher It will be analyzed by expert statistician

Participants/Inclusion and exclusion criteria

Criteria for entering the study include: Patients are in the age group of 50-70:able to answer questions:postmenopausal:Constipation according to Rome III:Not having the history of the diseases listed in the study:Not having drug and alcohol addiction:Not living in the nursing home. Exit criteria: Emergency and side effects during the intervention:Diet change to relieve constipation during the intervention period:Do not use dung more than 3 consecutive times a week:Critical and mental crisis, mourning, divorce, travel, illness

Intervention groups

Any one of the test group, 28 packs, 30 grams of husk will be delivered. Take one packet with two glasses of lukewarm water, take a glass of 30 minutes before breakfast and a glass for 30 minutes before dinner for four weeks. In the control group, they will drink a glass of water for four weeks in the morning and at night

Main outcome variables

Non-drug strategy for the treatment and prevention of constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190220042774N1**

Registration date: **2019-06-08, 1398/03/18**

Registration timing: **retrospective**

Last update: **2019-06-08, 1398/03/18**

Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name

Neda Khevegi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 58 3223 8901

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neda.kh232@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Descurainia sophia (L.) seed Webb ex Prantl on the severity of functional constipation in Women 50-70 years old .

Public title

Effect of Descurainia sophia (L.) seed Webb ex Prantl on the severity of functional constipation in Women 50-70 years old .

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in the age range of 50-70 years Mentally minded and able to answer questions. Postmenopause. Constipation according to Roman criteria III

Exclusion criteria:

The presence of diseases that the specialist confirms drug and alcohol addiction Attending the nursing home

Age

From **50 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

After identifying the subjects, to randomize the samples after the visit to the specialty of digestion and confirmation by him if the sample is approved for inclusion in the study, according to the 2nd bloc by the statistics expert, to the sample of the envelope (code Without name).(With random allocation based on patient referral) and the subjects were randomly assigned to control and intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assistant researcher, statistician

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Bojnourd University of Medical

Sciences

Street address

South Hospital Imam Ali Hospital,Shahriar Street

City

Bojnord

Province

North Khorasan

Postal code

9678694176

Approval date

2018-12-04, 1397/09/13

Ethics committee reference number

IR.NKUMS.REC.1397.070

Health conditions studied**1****Description of health condition studied**

Functional Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes**1****Description**

Frequency of bowel movements per week

Timepoint

Measure the severity of constipation at the beginning of the study (before the intervention) and the end of week 4 after the start of the descurainia sophia.

Method of measurement

Constipation Assessment Questionnaire(CAS)

Secondary outcomes

empty

Intervention groups**1****Description**

he 30-gram descurainia sophia packs are placed in the test group. Every night a packet with a glass of water is provided, the next day a glass of 30 minutes before breakfast and a glass of 30 minutes before dinner for 4 weeks will be consumed by the research unit.

Category

Treatment - Drugs

2**Description**

Control group: Take 2 glasses of water, a glass 30 minutes before breakfast and a glass 30 minutes before dinner for 28 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Social Security Hospital in Bojnourd

Full name of responsible person

Dr. Behzad Ramezani Farokhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr.Seyed Kaveh Hojjat

Street address

Central building of North Khorasan University of
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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Neda Khayahi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Master

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available