Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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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Chamran street

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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

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Central building of North Khorasan University of Medical Sciences,Government Boulevard

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S.Kavehhojjat1@gmail.com

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 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