

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### A clinical trial evaluating of effect of *Descurainia sophia* (L.) on clinical symptoms of adult patients with functional constipation

#### Protocol summary

##### Summary

Objective: evaluation of therapeutic effect of *Descurainia sophia* (L.) seeds on clinical symptoms of functional constipation in adults Study design: single-center clinical trial Study population: patients with chronic constipation referred to the gastroenterology clinic: Shariat Panahi clinic, School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran Main inclusion criteria: adult patients with chronic constipation who fulfilled inclusion criteria ROMIII for chronic functional constipation, and has no sever disease in liver, kidney and cardiovascular systems and announced their agreement to participate in the program by signing a voluntary and informed consent. Main exclusion criteria: Lack of durability of the above conditions; Unwillingness to continue participation in the study; Drug side effects or other threatening events. Sample size: 35 people Intervention Study: A warm syrup of *Descurainia sophia* (L.) seeds and sugar at fasting once daily

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016030515408N2**

Registration date: **2016-03-29, 1395/01/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-29, 1395/01/10

##### Registrant information

##### Name

Anahita Ghourchian

##### Name of organization / entity

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3463 5198

##### Email address

dr.anahitaghouchian@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2014-12-21, 1393/09/30

##### Expected recruitment end date

2015-12-21, 1394/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial evaluating of effect of *Descurainia sophia* (L.) on clinical symptoms of adult patients with functional constipation

##### Public title

A clinical trial evaluating of effect of *Descurainia sophia* (L.) on clinical symptoms of adult patients with functional constipation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age: 70-20 years at the time of screening; Ability to participate in the study and there is no obvious behavioral disorders, speech and language diaeres; No major abdominal surgery; Lack of self and

family history of thyroid disease; Colon cancer screening in people over 50 years; Lack of warning signs (rectal bleeding and weight loss and anemia); No underlying disease affecting constipation (Parkinson, Multiple sclerosis, stroke, hypothyroidism, cancer); Lack of pregnancy or lactation; Speaking ins; Avoiding the use of antibiotics in the past 5 weeks; Not taking medications causing constipation; No addiction; Complete the consent form; Having normal routine tests, including complete blood count, fecal occult blood test, alkaline phosphatase and TSH test, liver enzymes and Cr; No previous sensitivities to herbal medicines; Absence of severe cardiovascular disease, especially functional class 3 & 4 of chronic heart failure; Lack of proven malignancy; Absence of liver disease (esophageal varices and bleeding, encephalopathy, ascites); Absence of symptomatic gallstone disease (in history); Absence of severe kidney disease (creatinine more than 3 mg / dl); Having the criteria for functional constipation ROMIII. Main exclusion criteria: Lack of durability of the above conditions; Unwillingness to continue participation in the study; Drug side effects or other threatening events.

#### Age

From **20 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **35**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

##### Name of ethics committee

Office of Research Affairs, Deputy of Research and Technology, Shahid Beheshti University of Medical

##### Street address

Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh st., Yemen st., Shahid Chamran Highway

##### City

Tehran

##### Postal code

##### Approval date

2014-05-04, 1393/02/14

##### Ethics committee reference number

150

### Health conditions studied

#### 1

##### Description of health condition studied

Relationship of Descurainia sophia L. with functional constipation in adults

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

The proportion of patients reaching three or more spontaneous complete bowel movement/week

##### Timepoint

At the beginning, before the intervention and 4 weeks after, at the end of study

##### Method of measurement

By interviews with patients and asking them

### Secondary outcomes

#### 1

##### Description

The number of laxatives used

##### Timepoint

At the beginning, before the intervention and 4 weeks after, at the end of study

##### Method of measurement

By interviews with the patients and asking them

#### 2

##### Description

The score of a check list of Patient Assessment of Constipation Symptoms (PAC-SYM) items

##### Timepoint

At the beginning, before the intervention and 4 weeks after, at the end of study

##### Method of measurement

By interviews with the patients and asking them

#### 3

##### Description

The type of stool according to Bristol chart

##### Timepoint

At the beginning, before the intervention and 4 weeks after, at the end of study

##### Method of measurement

By interviews with the patients and asking them

## Intervention groups

1

### Description

Intervention: A spoonful of dry seeds of *Descurainia sophia* L. and a spoonful of sugar in a cup of boiling water are mixed and taken at fasting once a day. If the properties of defecation do not satisfy the patient, he is allowed to increase the dose of drug every three days to a maximum of 6 teaspoons / day.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Dr. Shariat Panahi Clinic

#### Full name of responsible person

Dr. Rasool Choopani

#### Street address

No.8 Shams Alley, opposite St Tavanir, Vali Asr Street

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Be

#### Full name of responsible person

Dr. Rasool Choopani

#### Street address

No.8 Shams Alley, opposite St tavanir, Vali Asr Street

#### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Be

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe

#### Full name of responsible person

Dr. Anahita Ghourchian

#### Position

Ph.D student of Traditional Medicine

#### Other areas of specialty/work

#### Street address

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#### Web page address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe

#### Full name of responsible person

Dr.Rasool Choopani

#### Position

M.D, Ph.D and Assistant Professor of Traditional Medicine

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe

**Full name of responsible person**

Dr. Anahita Ghourchia

**Position**

MD, PhD candidate of Traditional Medicine

**Other areas of specialty/work****Street address**

No.8 Shams Alley, opposite St Tavanir, Vali Asr Street

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**Email**

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anahitaghourchian@gmail.com

**Web page address**

<http://traditional.sbm.ac.ir>

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*