

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of Sisymbrium Sophia on functional constipation in comparison with poly ethylene glycol in 2-12 y/o children

Protocol summary

Summary

The goals The effect of descurainia Sophia in treatment of functional constipation in children 2-12 y/o (a randomized controlled clinical trial) The effect of descurainia Sophia in frequency of bowel habits in children(2-12 y/o) with functional constipation The effect of descurainia Sophia in frequency of firm stool in children(2-12 y/o) with functional constipation The effect of descurainia Sophia in frequency of encopresis in children(2-12 y/o) with functional constipation The effect of descurainia Sophia in frequency of painful bowel habits in children(2-12 y/o) with functional constipation The effect of descurainia Sophia in frequency of blood stained stool in children(2-12 y/o) with functional constipation Design – participants First, the patients(2-12 y/o) who refer to Imam Reza children gastroenterology clinic, are visited by a paediatrics gastroenterologist and the children who meet the Rom 3 criteria for functional constipation, refer to physician in Motahari clinic for completing the questionnaire. We ask the parents, about the onset and duration of constipation, painful defecation, feeling of abdominal fullness, eating habits, medication, and feeling of incomplete evacuation, stool consistency, stool colour and the history of laxatives use in children. Inclusion exclusion criteria The children should have at least two criteria from Rom 3 for functional constipation and lack of rome 3 criteria for IBS Interventions The sample size regarding to literature estimated 120 that in each group 60 patients based on blocked randomization, and polyethylene glycol or flaxseed prescribe for 3 weeks. On the end of each week and after terminating the course of drug therapy. the questionnaire is completed. After completion of sample size the data are processed by SPSS. Variables of main outcome Frequency of bowel habits per week Frequency of firm stool per week Frequency of encopresis per week Frequency of painful defecation per week Frequency of blood stained stool per week

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011412126N1**

Registration date: **2013-01-21, 1391/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-21, 1391/11/02

Registrant information

Name

Majid Nimrouzi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1628 8910

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences Shiraz university of medical sciences

Expected recruitment start date

2013-01-15, 1391/10/26

Expected recruitment end date

2013-07-01, 1392/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Sisymbrium Sophia on functional constipation in comparison with poly ethylene glycol in 2-12 y/o children

Public title

Effect of flixweed in children constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: functional constipation based on Rom3 criteria and age between 2 to 12 years. Exclusion criteria: organic cause constipation and irritable bowel syndrome criteria based on Rome3.

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Research Institute for Islamic and Complementary Medicine , Pynia Alley, Lalezarno Ave. Jomhoori Eslami St. Tehran, IRAN

City

Tehran

Postal code

1145847111

Approval date

2012-12-18, 1391/09/28

Ethics committee reference number

ت ط م 26 957

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 habit per week

Timepoint

before intervention, 0-1-2-3 week after intervention

Method of measurement

rome 3 standard questionnaire

2

Description

frequency of bulky solid stool per week

Timepoint

before intervention, 0-1-2-3 week after intervention

Method of measurement

standard q rome3

3

Description

frequency of encopresis per week

Timepoint

before intervention, 0-1-2-3 week after intervention

Method of measurement

standard q rome3

4

Description

frequency of painful bowel habit per week

Timepoint

before intervention, 0-1-2-3 week after intervention

Method of measurement

standard q rome3

5

Description

frequency of bloody stool per week

Timepoint

before intervention, 0-1-2-3 week after intervention

Method of measurement

standard q rome3

Secondary outcomes

empty

Intervention groups

1

Description

control: polyethylene glycol 3gr before 4y/o and 6 gr 5 y/o and upper for 3 weeks and daily(Qod)

Category

Treatment - Drugs

2

Description

case: descurnia sophia syrup 2gr before 4y/o and 3gr 5y/o and upper for 3 weeks and daily(Qod)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari clinic

Full name of responsible person

Majid Nimrouzi

Street address

Nemazee square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad bagher minaei

Street address

Tehran school of traditional medicine- Behesht street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran university of medical sciences

Full name of responsible person

Majid Nimrouzi

Position

PhD student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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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