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 is 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 flixweed 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)
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Recruitment status

Recruitment complete

Funding source

Tehran univirsity of medical sciencesShiraz univirsity 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
Iclusion 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 , Pyrnia 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
26 957 ت ط م

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
frequncy 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: descurainia 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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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tehran university of medical sciences
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majid nimrouzi
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PhD student intraditional medicine
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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