Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sugarcane extract syrup in comparison with PEG syrup (40%) in treatment of chronic constipation in children aged 4 to 12 years

Protocol summary

Summary

Objective: The effect of sugarcane extract syrup in comparison with PEG syrup (40%) in treatment of chronic constipation in children aged 4 to 12 years. Design: The study is designed to be two-sided blind and 90 children aged 4 to 12 years old with functional constipation who have criteria for Rome III and referred to Imam Reza clinic will be included in the trial. Setting and conduct: The patients are examined by a pediatric gastroenterologist and referred to the person who give them either of the syrups. Patients were divided into 2 randomized groups based on Blocked Randomization method. The syrups will be formulated and standardized under supervision of Departments of Pharmacognosy and Pharmaceutics of School of Pharmacy, Shiraz University of Medical Sciences. Syrups will have similar organoleptic properties. Participants including major eligibility criteria: Children aged 4 to 12 years; Chronic functional constipation; having at least 2 of the 6 Rome III criteria. Exclusion criteria: Taking any type of laxative 4 weeks before the trial; diabetes, autoimmune diseases, hypothyroidism, cystic fibrosis, history of intestinal surgery. Intervention: Group A will receive sugarcane extract syrup, 1-1.5 milliliter per kilogram of body weight, daily. Group B will receive polyethylene glycol syrup (PEG 40%), 1-1.5 milliliter per kilogram of body weight, daily. Main outcome majors: Frequency of bowel habit per week; Frequency of painful bowel habit per week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710219204N2**
Registration date: **2017-11-09, 1396/08/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-11-09, 1396/08/18

Registrant information

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Azadeh Hamedi
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sugarcane extract syrup in comparison with PEG syrup (40%) in treatment of chronic constipation in children aged 4 to 12 years

Public title

The effect of sugarcane extract syrup in comparison with polyethylene glycol syrup (PEG 40%) in treatment of chronic constipation in children aged 4 to 12 years

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Children aged 4 to 12 years; Chronic functional constipation; having at least 2 of the 6 Rome III criteria Exclusion criteria: Taking any type of laxative 4 weeks before the trial; diabetes, autoimmune diseases, hypothyroidism, cystic fibrosis, history of intestinal surgery
Age
From **4 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Vice-Chancellor for Research in Shiraz University of Medical Sciences
Street address
Postal Code: 71345-1978; Central Building of Shiraz University of Medical Sciences, Zand Avenue. Shiraz, Iran
City
Shiraz
Postal code
Approval date
2017-02-14, 1395/11/26
Ethics committee reference number
IR.SUMS.REC.1395.181

Health conditions studied

1

Description of health condition studied
Functional Constipation
ICD-10 code
K59.0
ICD-10 code description
Functional Constipation

Primary outcomes

1

Description
Frequency of bowel habit per week
Timepoint
Before intervention, two and four weeks after intervention
Method of measurement
Rome III standard questionnaire

Secondary outcomes

1

Description
Frequency of painful bowel habit per week
Timepoint
Before intervention, two and four weeks after intervention
Method of measurement
Rome III standard questionnaire

2

Description
Possible serological side effects
Timepoint
Before intervention, four weeks after intervention
Method of measurement
Serlogical tests

Intervention groups

1

Description
Group A, for 1 month will receive sugarcane extract syrup, 1-1.5 milliliter per kilogram of body weight, daily.
Category
Treatment - Drugs

2

Description
Group B, for 1 month will receive polyethylene glycol syrup (PEG 40%), 1-1.5 milliliter per kilogram of body weight, daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Department of Imam Reza Clinic
Full name of responsible person
Dr. Azadeh Hamedi; Dr. Seyed Mohsen Dehghani
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr ali poustfroush zadeh
Street address
Postal Code: 71345-1978; Central Building of Shiraz University of Medical Sciences, Zand Avenue. Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz Univesity of Medical Sciences
Full name of responsible person
Dr. Azadeh Hamedi; Dr. Seyed Mohsen Dehghani
Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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00
Fax
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Web page address

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