

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

###### Name

Azadeh Hamedi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3242 4127

###### Email address

hamediaz@sums.ac.ir

##### 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

Serological 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 University of Medical Sciences

**Full name of responsible person**

Dr. Azadeh Hamedi; Dr. Seyed Mohsen Dehghani

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Imam Reza Clinic, Zand Avenue

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**Person responsible for updating data**

**Contact**

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**Full name of responsible person**

Dr. Azadeh Hamedi

**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

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**Fax**

**Email**

**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*