

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of brown sugar on functional constipation compared to poly ethylene glycol in children

Protocol summary

Summary

The plan of this study is to compare efficacy of brown sugar syrup and poly ethylene glycol (PEG) for treatment of constipation in children. 122 children above 2 years old suffering from functional constipation will be studied. The study is pilot, randomized and open label (not blinded). Patients will be recruited in two groups (n=61) and one of the above medication will be administered for four weeks. Defecation, constipation, number of defecations and drug adoption will be assessed. Inclusion criteria is children above 2 years old with functional constipation and Exclusion criteria are hypothyroidism; hirschprung Disease and congenital anomalies. Location of study is Amir Almomenin Hospital, Semnan, Iran.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061722794N1**

Registration date: **2015-07-24, 1394/05/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name

Bahador Bagheri

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 326 8059

Email address

bagherib@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Semnan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of brown sugar on functional constipation compared to poly ethylene glycol in children

Public title

The effect of brown sugar on functional constipation compared to poly ethylene glycol in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children above 2 years old with functional constipation
Exclusion criteria: Hypothyroidism; Hirschprung Disease; Congenital anomalies

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

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**

Ethics Committee, Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Postal code**Approval date**

2015-06-17, 1394/03/27

Ethics committee reference number

IR.SEMUMS.REC.1394.17

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**

Defecation

Timepoint

2 week and 4 week

Method of measurement

Parents

2**Description**

Constipation

Timepoint

2 week and 4 week

Method of measurement

Parents

3**Description**

Number of defecations

Timepoint

2 week and 4 week

Method of measurement

Parents

Secondary outcomes**1****Description**

Drug adoption

Timepoint

Every day

Method of measurement

Parents

Intervention groups**1****Description**

Control group: Patients will receive 2 mg/kg poly ethylene glycol for two weeks, if successful it will be continued for the next two weeks.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients will receive 2 mg/kg poly ethylene glycol for two weeks, if successful it will be continued for the next two weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir Almomnin Hospital

Full name of responsible person**Street address**

Amir Al momenin hospital, Mostafa Khomeini Blvd

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Semnan University of Medical Sciences

Full name of responsible person

Dr. Ali Rashidipour

Street address

Semnan

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Bahador Bagheri

Position

Assitant professor of pharmacology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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