Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 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)

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+98 912 326 8059

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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
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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