Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of coadministration of polyethylene glycol and fig syrup for the treatment of chronic functional constipation in children

Protocol summary

Study aim
Determination and comparison of the effect of simultaneous administration of polyethylene glycol and fig syrup on the treatment of chronic constipation in children

Design
Double-blind, randomized clinical trials

Settings and conduct
All types of drugs used with the same label, which are labeled only by the consultant's pharmacist, are available to the researcher. The distribution method is that 3 cards with different colors are placed in front of the patient and the patient chooses one. Each color is one of three models of syrup. The patient information form is also reserved for the physician's secretary, and the physician and researcher are not aware of it.

Participants/Inclusion and exclusion criteria
Entry Criteria: Chronic functional constipation, ages 2 to 15 years, lack of large and small intestinal diseases, insensitivity to figs or polyethylene glycols, lack of bowel obstruction, lack of kidney or heart failure. Exit criteria: the development of diarrhea following drug use and unwanted allergic reactions following drug intake, lack of cooperation and desire of the individual during the study to continue the company

Intervention groups
The first group consume 5 ml of fig juice every 3 times each day. The second group daily consumes 1 g / kg of body weight water soluble polyethylene glycol powder, and the third group daily uses 3 times and each time 5 ml of fig juice and 1 g per kilogram body weight of water soluble polyethylene glycol powder They do.

Main outcome variables
Evaluation and comparison of chronic functional constipation based on interviews and checklist in intervention groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N2**
Registration date: **2018-08-15, 1397/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-15, 1397/05/24**
Update count: **0**

Registration date
2018-08-15, 1397/05/24

Registrant information

Name
Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3650 3487

Email address
st_ansari.s@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-16, 1396/09/25

Expected recruitment end date
2018-08-24, 1397/06/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of coadministration of polyethylene glycol and fig syrup for the treatment of chronic functional constipation in children

Public title
Fig syrup effect on the treatment of chronic constipation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic functional constipation Age 2 to 15 years Lack of colon and small diseases Insensitivity to fig or polyethylene glycol Lack of bowel obstruction The absence of kidney or heart failure

Exclusion criteria:
Creating diarrhea after taking medication and creating unwanted allergic reactions following drug intake The lack of cooperation and the person's desire to continue the company during the study

Age
From **2 years** old to **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
All types of drugs used with the same label, which are labeled only by the consultant's pharmacist, are available to the researcher. The distribution method is that 3 cards with different colors are placed in front of the patient and the patient chooses one. Each color is one of three models of syrup. The patient information form is also reserved for the physician's secretary, and the physician and researcher are not aware of it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713492

Approval date
2017-12-10, 1396/09/19

Ethics committee reference number
IR.SKUMS.REC.1396.243

Health conditions studied

1

Description of health condition studied
chronic functional constipation

ICD-10 code
K59.00

ICD-10 code description
Constipation, unspecified

Primary outcomes

1

Description
The number of fecal excretions per week, the number of unwanted fecal excretions per week, the number of fecal excretions in the patient with pain, the number of times the patient experiences abdominal pain, the quality and consistency of fecal excretion

Timepoint
At the beginning of the study, 2, 4, 6 weeks after the start of the intervention

Method of measurement
Checklist provided by the parents of patients

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group:3 times a day, and take 5 ml of fig juice every time.

Category
Treatment - Drugs

2

Description
Second intervention group:1 g per kilogram body weight per day consumes water-soluble polyethylene glycol powder.
Category
Treatment - Drugs

3

Description
Third intervention group:3 times a day, and each time 5 ml of fig juice syrup and 1 g per kilogram body weight per day, they consume water-soluble polyethylene glycol powder.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Clinic
Full name of responsible person
Narges Maleki
Street address
Shariati Blvd., Imam Ali Clinic
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816788640
Phone
+98 38 3224 2696
Email
nmaleeky@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. seyed Kamal Solati(Associate Professor of Psychology)
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3334 2414
Email
nmaleeky@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Karamali Kasiri
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Shahrekord University of Medical Sciences, Building No. 2, University headquarters, Ayatollah Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3227 4004
Email
nmaleeky@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Karamali Kasiri
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Email

nmaleeky@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Karamali Kasiri

Position

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Email

nmaleeky@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidential information is kept.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information on the main consequence of sharing is possible.

When the data will become available and for how long

Start the access period 4 months after printing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete fundamental studies

From where data/document is obtainable

Hajar Hospital in Shahrekord nmaleeky@gmail.com

What processes are involved for a request to access data/document

Investigating the request of the researcher and providing sufficient documentation of his research and the reason for using the data can be provided.

Comments