

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 Ansari pour

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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Karamali Kasiri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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