

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of polyethylene glycol and lactulose in children with constipation

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determination of the effect of polyethylene glycol powder and lactulose syrup in children with constipation

Design

Randomized, unblinded, uncontrolled clinical trial with parallel groups

Settings and conduct

Children with chronic functional constipation referring to Hajar hospital in Shahrekord were randomly divided into two groups of 47 each. One group received polyethylene glycol and the other received lactulose. Fecal excretion, fecal incontinence, painful excretion, abdominal pain, as well as fecal consistency were recorded in a checklist before the intervention and 7, 14, and 21 days after the intervention. Painless excretion of stool with smooth or normal consistency at least three times a week is defined as success of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: chronic functional constipation

Exclusion criteria: ileus; renal failure; heart failure

Intervention groups

First intervention group received polyethylene glycol (Darupakhsh Pharmaceutical Co.) 3 gr (for children of 6 months or less) or 6 gr (for children of above 6 months) orally in three divided doses daily for 4 weeks. Second intervention group received lactulose (Darupakhsh Pharmaceutical Co.) 6 cc (for children of 6 months or less) and 12 cc (for children of above 6 months) orally in three divided doses daily for 4 weeks.

Main outcome variables

constipation

Last update: **2019-11-08, 1398/08/17**

Update count: **0**

Registration date

2019-11-08, 1398/08/17

Registrant information

Name

Karamali Kasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

kasiri.k@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of polyethylene glycol and lactulose in children with constipation

Public title

The effect of polyethylene glycol and lactulose in children with constipation

Purpose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044239N1**

Registration date: **2019-11-08, 1398/08/17**

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic functional constipation

Exclusion criteria:
Ileus Renal failure Heart failure

Age
From **1 year** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation of the participants to the intervention 1 and 2 groups will be done using random allocation software. Then, envelopes prepare according to the number of participants in the study. It will be recorded number one on the first envelope, the second envelope number 2, and etc. In each envelope, the assignment of each individual is determined by the software. In this way, the specified envelope for each individual will be opened and the individual will be assigned to one of the intervention 1 and/or intervention 2 groups according to the option recorded in the envelope.

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 of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology ,
Shahrekord University of Medical Sciences, Kashani
Blvd, Shahrekord,Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718765

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.SKUMS.REC.1398.074

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.00

ICD-10 code description

Constipation, unspecified

Primary outcomes

1

Description

constipation

Timepoint

Before the intervention and after 7, 14 and 21 days

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group received polyethylene glycol (Darupakhsh Pharmaceutical Co.) 3 gr (for children of 6 months or less) or 6 gr (for children of above 6 months) orally in three divided doses daily for 4 weeks.

Category

Treatment - Drugs

2

Description

intervention group 2: This group received lactulose (Darupakhsh Pharmaceutical Co.) 6 cc (for children of 6 months or less) and 12 cc (for children of above 6 months) orally in three divided doses daily for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Karamali Kasiri

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8819819854

Phone

+98 38 3222 0016

Email

kasiri.k@skums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor of Research and Technology
Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Kamal Solati

Street address

Vice Chancellor of Research and Technology
Shahrekord University of Medical Sciences, Kashani
Blvd, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

881954525

Phone

+98 38 3334 2414

Email

solati@skums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor of Research and Technology Shahrekord
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

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718761

Phone

+98 32220016

Email

kasiri.k@skums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Karamali Kasiri

Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

checklist information

When the data will become available and for how long

after data gathering

To whom data/document is available

Researchers

Under which criteria data/document could be used

publication of article

From where data/document is obtainable

Dr. Karamali Kasiri

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

after data gathering

Comments