# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of polyethylene glycol and lactulose in children with constipation

## Protocol summary

**Study aim**
Determination of the effect of polyethylene glycol powder and lactolose 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

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20190717044239N1**
Registration date: **2019-11-08, 1398/08/17**
Registration timing: **registered_while_recruiting**

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**

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

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Hajar Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran
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## 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**
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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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**