Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of Poly ethylene glycol and Lactulose effects on abdominal pain in children with fecal impaction and without ROME III criteria for constipation; (Occult constipation): a Randomized controlled study

Protocol summary

Study aim
Assessment of abdominal pain responding to Poly ethylene glycol vs Lactulose in patients with fecal impaction lacking ROME III criteria for constipation

Design
Pragmatic, community based, parallel group, double blind, randomised controlled trial

Settings and conduct
Patients were randomly stratified into two control and case groups. Case group was treated with Poly ethylene glycol for at least 2 weeks and control group was treated with Lactulose for at least 2 weeks. The abdominal pain was assessed by pain score scale from 1 to 10. Abdominal pain was assessed before and after treatment in both groups. Data was analysed using SPSS 23 software. Both participants and physicians were unaware of type of the prescribed medicine.

Participants/Inclusion and exclusion criteria
Inclusion criteria consists of patients at the age of 4 to 18 years, suffering from abdominal pain more than 14 days, and their abdominal pain lacks ROME III criteria for constipation. patients also have fecal impaction in abdominal X ray. Exclusion criteria consists of patients with history of abdominal surgery, hematochezia, antibiotic or laxative consumption in the last 2 weeks.

Intervention groups
Patients with abdominal pain lacking ROME III criteria were randomly devided into two groups. One group was treated with Poly ethylene glycol and another group was treated with Lactulose.

Main outcome variables
Abdominal pain rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181214041966N1**
Registration date: **2018-12-22, 1397/10/01**
Registration timing: **retrospective**

Last update: **2018-12-22, 1397/10/01**
Update count: **0**

Registration date
2018-12-22, 1397/10/01

Registrant information

Name
Mehran Hakimzade

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3443 9916

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hakimmehran@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Poly ethylene glycol and Lactulose effects on abdominal pain in children with fecal impaction and

without ROME III criteria for constipation; (Occult constipation): a Randomized controlled study

Public title
Effect of Poly ethylene glycol and Lactoluse on abdominal pain in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients at the age of 4 to 18 years patients with abdominal pain more than 14 days patients with abdominal pain lacking ROME III criteria for constipation patients with fecal impaction in abdominal X ray
Exclusion criteria:
Abdominal surgery Hematochezia Antibiotic consumption in the last 2 weeks Laxative consumption in the last 2 weeks
Age
From **4 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization is simple and its unit is individual. The random sequence was carried out using random number table. Concealment was also carried out through similar drug containers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The present study has designed as double blind. The participants were unaware of the medicines, as their care givers were asked to give the patients the prepared medications; in form of solution or syrup in similar containers, making them unrecognizable from each other for patients. Meanwhile, the physicians who were assessing the patients abdominal pain had no knowledge of type of medication.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapor University of Medical Sciences
Street address
Abuzar hospital, Parastar Blv, Ahvaz city
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2018-12-15, 1397/09/24
Ethics committee reference number
IR.AJUMS.REC.1396.901

Health conditions studied

1

Description of health condition studied
abdominal pain in pediatrics
ICD-10 code
R10.9
ICD-10 code description
Unspecified abdominal pain

Primary outcomes

1

Description
56% of patients suffered from moderate abdominal pain
Timepoint
before intervention and 2, 3, 4, 5, 6, 8, 12 weeks after intervention
Method of measurement
pain score scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients were treated with Poly ethylene glycol powder (Sepidaj Company, Iran) dissolved in water, at dose of 0.5 gr/kg every 12 h orally for at least two consecutive weeks. Chemically, Poly ethylene glycol is a water-soluble polymer with high molecular weight.
Category
Treatment - Drugs

2

Description
Control group: The patients were treated with Lactulose Syrup (Tolid daru Company, Iran), at dose of 0.5 cc/kg every 12 h orally, for at least two consecutive weeks. Chemically, Lactulose is a synthetic disaccharide composed of galactose and glucose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Abuzar hospital
Full name of responsible person
Mehran Hakimzade
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Ahvaz University of Medical Sciences
Full name of responsible person
Mehran Hakimzade
Position
Associate 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)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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