Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of pidrolax, paraffin and lactulose on chronic functional constipation in children aged 2-6 years referred to the pediatric clinic of Amirkabir Hospital

Protocol summary

Study aim

Compare the effect of pidrolax, paraffin and lactulose on chronic functional constipation in children aged 2 to 6 years referred to the pediatric clinic of Amirkabir Hospital

Design

Clinical trial with three parallel groups, single-blind, randomized, phase 3 on 150 patients. Random blocking method is used for randomization.

Settings and conduct

In this study, children aged 2 to 6 years referred to the pediatric clinic of Amirkabir Hospital in Arak, who according to the diagnosis of pediatric gastroenterologist are suffering from chronic constipation and have the inclusion criteria; Enter the study. These children will be divided into three identical groups (pidrolax, lactulose, paraffin) randomly. Then, the information of each child, including age, gender, number of defecations per week, stool consistency, etc. is monitored serially by asking checklists from the child or parents, so the information statistically analyzed. This study (due to differences in the form and type of drugs) is a single-blind study. In addition, by naming groups, we blind those who evaluate the results of the study.

Participants/Inclusion and exclusion criteria

All children with chronic constipation for at least 6 months aged 2 to 6 years referred to the pediatric clinic of Amirkabir Hospital Parental consent Do not have any disease other than constipation

Intervention groups

In the Pidrolax group, the child is given 0.7 gr per kg body weight orally in the morning of fasting. In the lactulose group 1 to 2 cc per kilogram daily and in the paraffin group, oral paraffin will be given in the amount of 0.5 cc per kg every 12 hours.

Main outcome variables

Number of defecation per week, stool consistency, number of abdominal pains per week, number of painful defection per week, anorexia and nausea. (Serial monitoring: before starting treatment, the first week after starting treatment, then every 2 weeks to two months)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211223053493N1**
Registration date: **2022-04-27, 1401/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-27, 1401/02/07**
Update count: **0**

Registration date

2022-04-27, 1401/02/07

Registrant information

Name

Fateme Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3368 4995

Email address

dr.f.heydari1400@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of pidrolax, paraffin and lactulose on chronic functional constipation in children aged 2-6 years referred to the pediatric clinic of Amirkabir Hospital

Public title

Comparison of the effect of pidrolax, paraffin and lactulose on chronic functional constipation in children aged 2-6 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All children with chronic constipation for at least 6 months aged 2-6 years referred to the pediatric clinic of Amirkabir Hospital Parental consent Do not have any disease other than constipation Absence of any psychiatric disorders in the child or parents No maintenance in welfare or other places than family Not to receive constipation treatment for 2 weeks before inclusion in the study Not being a single parent Absence of IBS according to ROME IV criteria Absence of mental retardation or metabolic disease (such as hypothyroidism), Hirschsprung or spinal anomalies or anorectal pathology Absence of gastrointestinal surgery Not to receive medical treatment affecting GI motility such as cisapride, motilium, erythromycin, loperamide

Exclusion criteria:

Lack of cooperation of parent or child Incidence of drug side effects and severe diarrhea Allergy to drugs

Age

From **2 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Children 2 to 6 years old referred to the clinic who have been diagnosed with chronic constipation based on the ROME4 diagnostic criteria will be divided into three equal groups (pidrolax, lactulose, paraffin) using random allocation. This study will be randomized. In order to perform random allocation, random blocking method with 6 blocks such as AABBCC, ABBACC, BBAACC, AACCBB, BBCCAA, ACBCAB, etc. will be used, which will have numbers from 1 onwards, respectively. Then, by randomly selecting numbers from 1 to n , (n = number of possible cases of six blocks) , random sequences of three types of drugs will be identified for the study samples. Drug A means pidrolax, drug B is lactulose and drug C is paraffin.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single-blind clinical trial study in which only the data analyzer is blinded and the data is provided to the data evaluator in groups A, B, and C. The patient, researcher, and clinical caregiver are aware and not blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Arak University of Medical Sciences

Street address

Alam al-Huda Street, Shahid Shiroodi Street, Arak

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۵

Approval date

2021-07-18, 1400/04/27

Ethics committee reference number

IR.ARAKMU.REC.1400.106

Health conditions studied

1

Description of health condition studied

Chronic functional constipation

ICD-10 code

K59.09

ICD-10 code description

Other constipation

Primary outcomes

1

Description

Primary consequence : Number of defecation per week

Timepoint

Before starting treatment, The first week after starting

treatment, Then every 2 weeks until two months later

Method of measurement

questionnaire

Secondary outcomes

1

Description

Secondary consequence : Stool consistency

Timepoint

Before starting treatment, The first week after starting treatment, Then every 2 weeks until two months later

Method of measurement

questionnaire

2

Description

Secondary consequence : Number of abdominal pains per week

Timepoint

Before starting treatment, The first week after starting treatment, Then every 2 weeks until two months later

Method of measurement

questionnaire

3

Description

Secondary consequence : Number of painful bowel movements per week

Timepoint

Before starting treatment, The first week after starting treatment, Then every 2 weeks until two months later

Method of measurement

questionnaire

4

Description

Secondary consequence : Anorexia

Timepoint

Before starting treatment, The first week after starting treatment, Then every 2 weeks until two months later

Method of measurement

questionnaire

5

Description

Secondary consequence : Nausea

Timepoint

Before starting treatment, The first week after starting treatment, Then every 2 weeks until two months later

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Intervention group 1: In Pidrolax group, the child is given 0.7 g / kg body weight (Sepidaj Pharmaceutical Company, Iran) orally in the morning fasting.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group: in the lactulose group 1-2 cc / kg / day (Exir Pharmaceutical Company, Iran) will be given.

Category

Treatment - Drugs

3

Description

Intervention group: Third intervention group: In the paraffin group, oral paraffin (Mahdaro Pharmaceutical Company, Iran) will be given in the amount of 0.5 cc per kg every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amirkabir Hospital

Full name of responsible person

Seyed Mojtaba Hashemi

Street address

Amirkabir Hospital, Parastar Square, Shahid Shiroodi St., Arak

City

Arak

Province

Markazi

Postal code

3819693181

Phone

+98 86 3313 4715

Email

info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Alam al-Huda St., Shahid Shiroodi St., Arak

City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۶۵
Phone
+98 86 3313 6055
Email
info@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Seyed Mojtaba Hashemi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Amirkabir Hospital, Parastar Square, Shahid Shiroodi St., Arak
City
Arak
Province
Markazi
Postal code
3819693181
Phone
+98 86 3313 4715
Email
mojtaba53hashemi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Nooshin Sadjadei
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Amirkabir Hospital, Parastar Square, Shahid Shiroodi St., Arak
City
Arak
Province
Markazi
Postal code
3819693181
Phone
+98 86 3313 4715
Email
nooshin1sadjadei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Fateme Heydari
Position
Medical intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Arash Building, Boostan Yek Alley, Hepco Street
City
Arak
Province
Markazi
Postal code
۳۸۱۸۸۱۷۳۱۲
Phone
+98 86 3368 4995
Email
dr.f.heydari1400@gmail.com
Web page address

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