

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Pidrolax plus paraffin versus Pidrolaxin the treatment of pediatric functional constipation

Protocol summary

Study aim

Comparison of Pidrolax plus paraffin versus Pidrolaxin the treatment of pediatric functional constipation

Design

The study will be double blind and clinical trial. 74 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients candidate for cpediatric functional constipation in Amirkabir Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is one-blind in which participant is kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Outpatients with a history of functional constipation (at least 3 months), 2 to 18 years
Exclusion criteria: Non-functional constipation, resistance to treatment in the first month, hypothyroidism, Hirschsprung's disease, Known disorders cardiac, renal and neurological, colon surgery history, patients with secondary constipation due to chronic disease such as endocrine, metabolic or neurological diseases

Intervention groups

Intervention group 1: will receive 0.7 geram in kilogeram Pidrolaxin in day for 3 months. Intervention group 2: will receive 0.7 geram in kilogeram in day of Pidrolaxin with liquid paraffin orally for 3 months.

Main outcome variables

Frequency of defecation , painful defecation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N179**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

Registration date

2023-01-01, 1401/10/11

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pidrolax plus paraffin versus Pidrolaxin the treatment of pediatric functional constipation

Public title

Comparison of Pidrolax plus paraffin versus Pidrolaxin the treatment of pediatric functional constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Outpatients with a history of functional constipation (at least 3 months) 2 to 18 years

Exclusion criteria:
Non-functional constipation Resistance to treatment in the first month hypothyroidism hyreshprong disease Known disorders cardiac, renal and neurological Colon surgery history Patients with secondary constipation due to chronic disease such as endocrine, metabolic or neurological diseases

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this controlled intervention trial, a blinding stage will be performed. In this way, two ready-to-use bottles of medicine labeled A and B will be prepared by the researcher: a bottle containing Pidrolox labeled (A) and a bottle containing liquid paraffin labeled (B). After randomization and grouping by the researcher, with the reference of each Which of the qualified patients will be delivered labeled bottles without the name of the drug (according to the grouping done) and the patient will not be informed of the type of drug treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committe Arak University Of Medical Sciences

Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
848176941

Approval date
2022-07-03, 1401/04/12

Ethics committee reference number
IR.ARAKMU.REC.1401.109

Health conditions studied

1

Description of health condition studied

Pediatric functional constipation

ICD-10 code

K59.9

ICD-10 code description

Functional intestinal disorder, unspecified

Primary outcomes

1

Description

Frequency of defecation

Timepoint

In week

Method of measurement

Physical examination

2

Description

Painful defecation

Timepoint

In week

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: will receive 0.7 geram in kilogeram Pidrolaxin in day for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group 2: will receive 0.7 geram in kilogeram in day of Pidrolaxin with liquid paraffin orally for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Noshin Sajadi

Street address

Amirkabir hospital, Parastar square, Arak

City

Arak

Province

Markazi

Postal code

848176941

Phone

+98 86 3417 3645

Email

sajadi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

dr Mahdi salehi

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

salehi@yahoo.com

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

Dr Mojtaba Hashemi

Position

Assistant of professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Amirkabir hospital, Parastar squire

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

hashemi@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr noshin Sajadi

Position

Assistant of professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Amirkabir hospital, Parastar squire

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax
+98 86 3222 2003
Email
sajadi@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Sepideh Jame bozorgi
Position
Medicine student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Payambar Azam Complex, Basij Square, Sardasht,
Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003

Fax
+98 86 3222 2003
Email
Sepide.jmb97@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