

# 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 pediatric 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 gram in kilogram Pidrolaxin in day for 3 months. Intervention group 2: will receive 0.7 gram in kilogram 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

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##### Province

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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

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##### Postal code

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##### 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

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## 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  
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Payambar Azam Complex, Basij Square, Sardasht,  
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**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