

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation Pidrolax powder and simultaneous use laxa plus syrup and Pidrolax powder in the pediatric functional constipation in patients 4 to 10 years old

Protocol summary

Study aim

Comparative evaluation between the Pidrolax with laxa plus and Pidrolax in the pediatric functional constipation in children 4 to 10 years old

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, sample size equal to 108 patients. Duration of treatment 2 months

Settings and conduct

Pediatric Clinic of Golpayegani Hospital in Qom

Participants/Inclusion and exclusion criteria

Functional constipation confirmed by ROME 3 criteria (At least 2 out of 6 criteria Rome III) Exclusion criteria: no bowel surgery and no hypothyroidism

Intervention groups

The intervention group was treated with Pidrolax plus Laxa plus and the control group was treated with Pidrolax plus placebo.

Main outcome variables

Constipation treatment

Mohammad Mohebbali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3366 1380

Email address

m.mohebbali47@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

2019-11-21, 1398/08/30

Actual recruitment end date

2020-06-21, 1399/04/01

Trial completion date

2020-08-22, 1399/06/01

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201029049185N1**

Registration date: **2020-11-26, 1399/09/06**

Registration timing: **retrospective**

Last update: **2020-11-26, 1399/09/06**

Update count: **0**

Registration date

2020-11-26, 1399/09/06

Registrant information

Name

Scientific title

Comparative evaluation Pidrolax powder and simultaneous use laxa plus syrup and Pidrolax powder in the pediatric functional constipation in patients 4 to 10 years old

Public title

Comparison between the Pidrolax and simultaneous use laxa plus and Pidrolax in the pediatric constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Functional constipation confirmed by ROME III criteria

Exclusion criteria:

Hypothyroidism and history of bowel surgery

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **108**

Actual sample size reached: **108**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients and their parents did not know the classification

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sari University of Medical Sciences

Street address

Imam Square (RA) Joibar three ways, the beginning of Valiasr Highway

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2019-11-16, 1398/08/25

Ethics committee reference number

IR.IAU.SARI.REC.1398.118

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.09

ICD-10 code description

Other constipation

Primary outcomes

1

Description

Constipation treatment

Timepoint

End of the second and fourth months after treatment

Method of measurement

Self-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group received Pidrolax plus Laxa plus medication regimen. Pidrolax 10 grams daily and 2.5 cc of Laxa plus

Category

Treatment - Drugs

2

Description

Control group: Patients in this group received Pidrolax plus placebo medication regimen. Pidrolax in the amount of 20 grams daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Clinic of Ayatollah Golpayegani Hospital, Qom

Full name of responsible person

Mohammad MohebAli

Street address

Motahhari Square, Rahbar Street

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Ghoum

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3714963744

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h.golpayegani@gmail.com

Sponsors / Funding sources

Sponsor**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Qolam Reaza Najafi

Street address

Pardisan, University Blvd.

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Mohmad Javad Qasem zade

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Islamic Azad University, next to Social Security Insurance, 15 Khordad Blvd., Shah Seyed Ali Square

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Email**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mohammad MohebAli

Position

physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mohammad MohebAli

Position

physician

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For researchers working in academic and scientific institutions

From where data/document is obtainable

Islamic Azad University of Qom

What processes are involved for a request to access data/document

By inserting the request in the email and replying after viewing the email

Comments