Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The comparison of efficacy of Pidrolax powder and Probiotic in the treatment of functional constipation in 4– 12 years old children

Protocol summary

Summary

The pourpose of this study is the effect of probiotic in the treatment of functional constipation in 4– 12 years old children . Methods: A single- blind randomized controlled study (RCT)was performed. 90 children aged 4- 12 years old with functional constipation according to rome III criteria were assessed for 4 weeks.They were randomized in 2 groups: Group A received 0.7-1.5gr/kg /day powder pydrolax per day. Group B: 2 sachet of probiotic plus 0.7-1.5gr/ kg /day powder pydrolax. Frequency of bowel movements (BMs), stool consistency, number of fecal incontinence episodes, abdominal pain, painful defecation per week, side effects were analyzed in each group before treatment and 2 and 4 weeks after institution of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041513021N1**
Registration date: **2014-05-09, 1393/02/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-09, 1393/02/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of efficacy of Pidrolax powder and Probiotic in the treatment of functional constipation in 4– 12 years old children

Public title

The effect of Probiotics in the treatment of functional constipation in 4– 12 years old children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 4-12 years old children; functional constipation[to rome III criteria], Exclusion criteria:consumption of laxative during last 4 weeks; mental retardation; hypothyroidism; cystic fibrosis and previous intestinal surgery.

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kurdistan University of Medical Sciences
Street address
Beast Farmer Street Hospital in Sanandaj
City
Sanandaj
Postal code
66177-13446
Approval date
2012-11-15, 1391/08/25
Ethics committee reference number
Paragraph 10 No. 14/28626 second meeting of Medical Ethics

Health conditions studied

1

Description of health condition studied
Functional constipation
ICD-10 code
k59.0
ICD-10 code description
Constipation

Primary outcomes

1

Description
Less than 3 times defecation per week
Timepoint
Before intervention and 2 and 4 weeks after institution of intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Abdominal pain
Timepoint
Before and afetr intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention:probiotic sachet plus powder PEG.
Category
Treatment - Drugs

2

Description
Control group:/7_1gr/kg/day pydrolax powder alone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric gasteroentrology subspeciality clinic : Besat Hospital : Sanandaj
Full name of responsible person
The patient's mother
Street address
Besat Hospitsal ; Keshavarz St.
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Fardin Gharibi
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Pasdaran St.Depeuty research.kurdistan University of Medical Sciences
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Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kurdistan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty