

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 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 purpose 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 pidrolax per day. Group B: 2 sachet of probiotic plus 0.7-1.5gr/ kg /day powder pidrolax. 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

###### Name

Banafshe Sedaghat

###### Name of organization / entity

Kurdistan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 1666 4646

##### Email address

bani.2010@muk.ac.ir

##### 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 gastroentrology 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

##### Street address

Pasdaran St.Depeuty research.kurdistan University of Medical Sciences

##### City

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

Sanandaj

**Postal code**

66177-13446

**Phone**

+98 87 1328 5419

**Fax**

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**Email**

bani.2010@muk.ac.ir; rasolabady@muk.ac.ir

**Web page address**

www.muk.ac.ir

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

Kurdistan University of Medical Sciences

**Full name of responsible person**

Sedaghat Banafsheh

**Position**

Assistant of pediatric diseases

**Other areas of specialty/work****Street address**

Beast Farmer Street Hospital in Sanandaj

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**Contact****Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Dr. Masomeh Abedini

**Position**

MD, Pediatric infectious diseases subspecialist

**Other areas of specialty/work****Street address**

Pediatric ward, Besat hospital

**City**

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66177-13446

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**Web page address**

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

Kurdistan University of Medical Sciences

**Full name of responsible person**

Dr Masomeh Abedini

**Position**

MD, Pediatric infectious diseases specialist

**Other areas of specialty/work****Street address**

Beast Farmer Street Hospital in Sanandaj

**City****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