

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of whey in the treatment of functional constipation in children aged 1 to 16 years old

Protocol summary

Study aim

Determination of the effect of whey in the treatment of functional constipation in children aged 1 to 16 years old referred to pediatric gastroenterology clinics in Yazd

Design

Clinical trials with community based and pragmatic control group, with parallel groups, without blindness, randomized

Settings and conduct

In this study, children aged 1 to 16 years with chronic functional constipation are included in the study. Patient information are recorded in the questionnaire. According to the randomized table, patients enter two groups. In one group of patients, pidrolax powder is weighed 0.8 grams per kilogram, and the other group of pidrolax powder is given the same amount of cheese and one cup a day for one month. pidrolax powder is adjusted every four days on the basis of soft and daily stools (with advice from parents). Patients on the 15th and 30th day of treatment will be asked for information on the frequency of feces, stool consistency, incontinence, drug intake, and drug complications. .

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 1 to 16 years old with functional constipation (based on Rome IV CR), Obtain parental consent to enter the study and enter it, Possible patient tracking
Exclusion criteria: Patients who have been examined in favor of organic constipation, Patients with neurological disorder, History of Anorectal Surgery, Patients who have taken medication more than six months before the study, Patients who use a drug other than Pidrolax.

Intervention groups

A group powder pidrolax and whey get Others will only receive pidrolax powder

Main outcome variables

duratio of defecation; stool consistency; fecal incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042459N1**

Registration date: **2019-02-11, 1397/11/22**

Registration timing: **prospective**

Last update: **2019-02-11, 1397/11/22**

Update count: **0**

Registration date

2019-02-11, 1397/11/22

Registrant information

Name

Fateme Motavasselian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 3907

Email address

motavasselianz@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of whey in the treatment of functional constipation in children aged 1 to 16 years old

Public title

The effect of whey in the treatment of functional constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 1 to 16 years chronic functional constipation for at least two months Based on Rome IV Criterion Acquiring parental consent to enter and study it Possibility of patient Follow up

Exclusion criteria:

Patients who have been diagnosed with a history of organic constipation Patients with neurological disorder History of Anorectal Surgery Patients who have taken medication more than six months before the study Patients who use a drug other than pidrolax

Age

From **1 year** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method using a random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Central office of Yazd Shahid Sadoughi University of Medical Sciences, Shahid Sadoughi Blvd

City

Yazd

Province

Yazd

Postal code

8951737915

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.SSU.REC.1397.115

Health conditions studied

1

Description of health condition studied

Constipation of children

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Times of defecation

Timepoint

At first, 15 and 30 days after taking the drug

Method of measurement

Parental statements(times in week) Through the questionnaire

2

Description

Stool consistency

Timepoint

At first, 15 and 30 days after taking the drug

Method of measurement

Bristol stool chart

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To a group of patients, Pidrolax powder is given at a dose of 0.8 g / kg , and whey is made by Niak Company for one month (120 cc) per day for one month. The amount of Pidrolax powder is adjusted every four days on the basis of soft and daily stools (with advice to parents). On the 15th and 30th day of the treatment, information on the frequency of defecation, stool consistency, incontinence, drug intake, and complications of the drugs are asked.

Category

Treatment - Drugs

2

Description

Control group: To a group of patients, Pidrolax powder is given at a dose of 0.8 grams per kilogram of daily weight for one month. The amount of Pidrolax powder is adjusted every four days on the basis of soft and daily stools (with advice to parents). On the 15th and 30th day of the treatment, information on the frequency of defecation, stool consistency, incontinence, drug intake, and complications of the drugs are asked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al anbia Clinic

Full name of responsible person

Fateme Motavasselian

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Taleghani Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzayi

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fateme Motavasselian

Position

Phd candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Majid Emtiazy

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Fateme Motavasselian

Position

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Latest degree

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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