

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of cow's milk effect on chronic persistent functional Constipation in children

Protocol summary

Study aim

Choosing the right method for the treatment of refractory chronic functional constipation in children

Design

Two arm parallel group randomised trial with postoperative care and outcome assessment

Settings and conduct

In this clinical trial, all children with chronic functional constipation in age from 4 to 14, and in the year to come Amirkola Clinic Hospital, were enrolled in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 14.4 years, failure to respond to treatment with laxatives, functional constipation, including: delays in the disposal of meconium and weight loss and abdominal pain, nausea and vomiting can not be justified. Exclusion criteria: Anatomical causes of constipation, constipation cause Saykomotor disorders (hypothyroidism), anal surgery, medications that cause constipation and urinary tract infections and urinary incontinence.

Intervention groups

Intervention group: Group A cow's milk-free diet + 0.5 g / kg / day Pidrolax laxative (Company Sepidaj Karaj) for 4 weeks and for all patients in the first group of calcium syrup at a dose of 30 mg kg Klsieram factory was Ramofam. Control group: Group B diet containing cow's milk + 0.5 g / kg / day Pidrolax laxative (Company Sepidaj Karaj) for 4 weeks.

Main outcome variables

Frequency of bowel habit per week, Frequency of painful bowel habit per week, Reduced resistance to laxative therapy, Reducing the need for therapeutic dose of laxative

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190306042946N1**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Atena Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 6963

Email address

mohamatena@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-02, 1397/12/11

Expected recruitment end date

2020-03-01, 1398/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of cow's milk effect on chronic persistent functional Constipation in children

Public title

Evaluation of cow's milk effect on chronic persistent

functional Constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 14.4 years and , can not be justified. Failure to respond to treatment with laxatives Functional constipation delays in the disposal of meconium weight loss Unexplained abdominal pain nausea and vomiting

Exclusion criteria:

Anatomical causes of constipation Constipation cause Saykomotor disorders hypothyroidism Anal surgery Medications that cause constipation Urinary tract infections and urinary incontinence

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided into two groups by a simple random method. In this research, the coin toss will be used to create a random sequence in a two-group trial. So that one of the study groups is tail and the other group is considered as a head, and according to the sample size, the same amount of coin is tossed and the subjects are divided into two groups of random allocation.

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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.291

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Frequency of bowel habit per week

Timepoint

Before intervention and four weeks after intervention

Method of measurement

Rome III standard questionnaire

Secondary outcomes

1

Description

Frequency of painful bowel habit per week

Timepoint

Before intervention and four weeks after intervention

Method of measurement

Rome III standard questionnaire

2

Description

Reduced resistance to laxative therapy

Timepoint

Before intervention and four weeks after intervention

Method of measurement

Rome III Standard questionnaire

3

Description

Reducing the need for therapeutic dose of laxative

Timepoint

Before intervention and four weeks after intervention

Method of measurement

Rome III Standard questionnaire

Intervention groups

1

Description

Intervention group: Group A cow's milk-free diet + 0.5 g / kg / day Pidrolax laxative (Company Sepidaj Karaj) for 4 weeks and for all patients in the first group of calcium syrup at a dose of 30 mg kg Klsieram factory was Ramofam.

Category

Treatment - Drugs

2

Description

Control group: Group B diet containing cow's milk + 0.5 g / kg / day Pidrolax laxative (Company Sepidaj Karaj) for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital Shafizadeh Amirkola

Full name of responsible person

Dr. Sanaz Mehrabani Tabari

Street address

Children's Hospital Shafizadeh Amirkola, Babol

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amirkola_hospital1342@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Atena Mohammadi Borkhili

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Sanaz Mehrabani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

-

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available