Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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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
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Person responsible for updating data

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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