Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assesment the effect of synbiotic in the treatment of functional abdominal pain in children

Protocol summary

Study aim
Assesment the effect of synbiotic in the treatment of functional abdominal pain in children compared to placebo.

Design
A double blind clinical trial with an intervention group and a control group with 68 samples, randomized.

Settings and conduct
This is a double-blind clinical trial. In this study, 64 children aged 5-14 years with functional abdominal pain (FAP) referring to Amirkola Children's Hospital randomly will be divided into two groups of case and control. The case group will receive synbiotic and the control group will receive placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: FAP Detection based on Rome III criteria. Exclusion criteria:Immune deficiency; consumption of probiotics or prebiotics within 7 days prior to participating in the study; no antibiotic use during a recent month; chronic underlying disease, and ...

Intervention groups
Intervention group: Daily, 2 Sinobiotic sachets are consumed every 12 hours soluble in water or juice for one month. Control group:Daily, 2 Placebo are consumed every 12 hours soluble in water or juice for one month.

Main outcome variables
Frequency of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190304042914N1**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **registered_while_recruiting**
Last update: **2019-05-25, 1398/03/04**
Update count: **0**

Registration date
2019-05-25, 1398/03/04

Registrant information

Name
Azadeh Gholizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3234 6963

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-19, 1397/11/30

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assesment the effect of synbiotic in the treatment of functional abdominal pain in children

Public title
Assessment the effect of a drug in the treatment of abdominal pain in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

FAP diagnosis based on Rome III criteria

Exclusion criteria:

Immunodeficiency Consumption of probiotics or prebiotics within 7 days before participating in the study Chronic underlying disease Malignancy The presence of red flags includes a pain that awakens the baby Continuous pain of RUQ or RLQ Vomiting (biliary, frequent, periodic, or disturbing for the physician) Fever without cause Urogenital Symptoms Dysphagia Severe chronic diarrhea or Nocturnal diarrhea Gastrointestinal bleeding Unwanted weight loss Downtrend in the growth curve Delayed puberty Family history of IBD Celiac and PUD Localized tenderness in RUQ or RLQ Localized mass Splenomegaly Jaundice CVA tenderness Arthritis Vertebral tenderness Disease in the perianal area Abnormal or unreasonable findings in the examination Hematochezia Anemia Hepatomegaly Antibiotic use in the last month

Age

From **5 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using a computer and a random number system. Patients are divided into two groups A and B and drugs are coded.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double blind study, both participants and searcher are unaware of the allocation of study groups to the two groups that receive the drug and the group B receiving the placebo.

Placebo

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

Ganjafroz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.270

Health conditions studied

1

Description of health condition studied

Functional abdominal pain

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes

1

Description

Frequency of pain

Timepoint

At the beginning of the study and one month after the start of treatment.

Method of measurement

check list

Secondary outcomes

1

Description

Number of absentee days from school

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Check list

2

Description

Pain intensity

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Face scaling

Intervention groups

1

Description
Intervention group: Daily, 2 Sinobiotic sachets are consumed every 12 hours soluble in water or juice for one month.
Category
Treatment - Drugs

2

Description
Control group:Daily, 2 Placebo are consumed every 12 hours soluble in water or juice for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Children’s Hospital
Full name of responsible person
Azadeh Gholizadeh
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No 19, Amirkola Children’s Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Reza Ghadimi
Street address
Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street
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Web page address
http://research.mubabol.ac.ir/
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
Azadeh gholizadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Other areas of specialty/work
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Person responsible for updating data

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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
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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable