Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the Effectiveness of Domperidon with Placebo in the treatment of Functional Abdominal Pain in children

Protocol summary

Study aim
Comparison of treatment with Domperidone and Placebo in children with Functional Abdominal Pain

Design
Clinical trial with control group, Block randomized parallel groups,phase 3, on 80 patients

Settings and conduct
After the diagnosis of FAP was made by a pediatric gastroenterologist for 5 to 14 years old patients who referred to Amirkola Children's Hospital, the patient was referred to a knowledgeable nurse for research. She will place the samples in 2 categories using Block randomized. A group of domperidone tablets 0.25 mg per kg TDS (Hakim Pharmaceutical Company) for 8 weeks and placebo that is completely similar in shape, appearance and color to domperidone (Sari University of Medical Sciences Faculty of Pharmacy) were given in the other group. Before the start of the study and after two months of treatment, a questionnaire containing questions about the duration of pain, pain intensity and frequency of pain (based on the number of days) will be completed by a pediatric assistant with gastroenterology supervision. Pain intensity assessment will be done based on Wong-Bake FACES Pain Rating Scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 5 to 14 years old Children who referred to Amirkola Children's Hospital with Functional Abdominal Pain (FAP) Exclusion Criteria: presence of chronic disease, use of other drugs such as probiotics and antibiotics during the month before the start of the project, the presence of abdominal pain's red flags, constipation

Intervention groups
A group of domperidone tablets 0.25 mg per kg TDS (Hakim Pharmaceutical Company) for 2 months and placebo that is completely similar in shape, appearance and color to domperidone (Sari University of Medical Sciences Faculty of Pharmacy) were given in the other group

Main outcome variables
Change at least 50% of the frequency of pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160308026973N2**
Registration date: **2021-01-08, 1399/10/19**
Registration timing: **prospective**

Last update: **2021-01-08, 1399/10/19**
Update count: **0**

Registration date
2021-01-08, 1399/10/19

Registrant information
Name
Sanaz Mehrabani
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-20, 1399/11/01
Expected recruitment end date
2021-06-22, 1400/04/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Domperidon with Placebo in the treatment of Functional Abdominal Pain in children

Public title

Assesment the effect of Domperidone in the treatment of Functional Abdominal Pain in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

5-14 years old children referred to Amirkola Children's Hospital with diagnosis of functional abdominal pain (FAP)

Exclusion criteria:

Existence of chronic disease Taking other medications such as antibiotice and probiotic during the month before the start of the project The presence of Abdominal pain's red flags Constipation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The research-aware nurse divided the samples into 2 categories using Block randomized. Both the physician and the patient will be blind to the grouping of patients (Double blind)

Blinding (investigator's opinion)

Double blinded

Blinding description

After the diagnosis of FAP was given to the patients by the Pediatric Gastroenterologist and the initial questionnaires were completed by the Pediatric assistant under the supervision of the Pediatric Gastroenterologist, the patient was referred to a knowledgeable nurse for research. She will place the samples in 2 categories using Block randomized .

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

No 19, Amirkola Children’s Hospital, Amirkola,

City

Babol

Province

Mazandaran

Postal code

4731741151

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.MUBABOL.REC.1399.320

Health conditions studied

1

Description of health condition studied

Functional Abdominal Pain

ICD-10 code

K59.9

ICD-10 code description

Functional intestinal disorder, unspecified

Primary outcomes

1

Description

Change at least 50% of the frequency of pain

Timepoint

At the beginning of the study and after two months of medication (end of the study)

Method of measurement

Based on the questionnaire of reducing the frequency of pain, pain intensity and duration of pain (assessment of pain intensity based on face scale questionnaires)

Secondary outcomes

1

Description

Abdominal pain intensity based on Wong-Baker FACES Pain Rating Scale questionnaire

Timepoint

At the beginning of the study (before the intervention) and after two months of medication (end of the study)

Method of measurement

Wong-Baker FACES Pain Rating Scale questionnaire

2

Description
Duration of pain
Timepoint
At the beginning of the study (before the intervention) and after two months of medication (end of the study)
Method of measurement
Attached questionnaire at the end of the proposal (based on patient statements)

3

Description
Pain frequency (number of pain days per month)
Timepoint
At the beginning of the study (before the intervention) and after two months of medication (end of the study)
Method of measurement
Attached questionnaire at the end of the proposal (based on patient statements)

Intervention groups

1

Description
Intervention group: Domperidone tablets 0.25mg / kg TDS up to 8 weeks (Hakim Pharmaceutical Company)
Category
Treatment - Drugs

2

Description
Control group: Placebo which is completely similar to Domperidone in terms of shape, appearance and color (Faculty of Pharmacy, Sari University of Medical Sciences)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Children’s Hospital
Full name of responsible person
Dr Sanaz Mehrabani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Negin Tavackoli Haghighi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data including primary (before treatment) and secondary (end of treatment) questionnaires including patients' demographic information, pain frequency, pain intensity and duration of pain can be shared after the individuals not being identified.

When the data will become available and for how long
Documents are available forever after the results are published.

To whom data/document is available
The documentation will be accessible to everyone.

Under which criteria data/document could be used
It is possible to use the documents in other scientific articles and to obtain new results in different contexts while submitting a written request and agreeing to be responsible for the study response.

From where data/document is obtainable
It is possible to receive documents from the Research Center of Babol University of Medical Sciences (Babol University of Medical Sciences located in Ganj Afrooz St.) or by correspondence with the person in charge of public accountability of the study via email (n.tavackoli.h@gmail.com).

What processes are involved for a request to access data/document
It is possible by submitting a request in person or by e-mail through the said addresses.

Comments