# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
Babol University of Medical sciences

**Country**
Iran (Islamic Republic of)

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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**

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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**
Pediatrics
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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**