Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the efficacy of Buspirone and placebo in functional abdominal pain in children

Protocol summary

Study aim

Comparison of the efficacy of Buspirone and placebo in functional abdominal pain in children

Design

In this study, 100 children with the diagnosis of functional abdominal pain who are eligible for the study are chosen from a pediatrics gastroenterology private clinic. They are then randomly assigned into two groups of intervention and control and receive buspirone or placebo. Medications are placed in bottles that are divided by a pharmacist through a randomization software and each bottle have a code. This trial is a Phase 3 clinical trial.

Settings and conduct

In this study patients are recruited from a pediatrics gastroenterology private clinic, based on the inclusion criteria that has been explained in the study protocol. At first, patients will be observed for one week for type of their symptoms and pain severity without using any medications. Then patients would receive placebo or buspirone which are in matte bottles, randomly for 4 weeks. These bottles are classified randomly through the randomization software by a pharmacist. In each arm of the study, 50 patients are involved based on the statistical calculations. To determine the efficacy of buspirone and to compare its efficacy with placebo, two primary and secondary outcomes are defined. Primary outcome measure treatment response as pain relief in patients using Wong-Baker faces pain rating scale (WBFPRS). Secondary outcome measures the amount of changes in depression severity, anxiety, somatization, sleep quality and clinical impression of severity and improvement from the physician's point of view through The Children's Depression Inventory (CDI), Revised children's manifest anxiety scale TM(RCMASTM), Children's Somatization Inventory-Revised Form (CSI-24), The Sleep Disturbance Scale for Children (SDSC) and Clinical Global Impression Severity and Improvement scales (CGI-S, CGI-I) respectively. Primary and secondary outcomes are measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention. Side effects also would be evaluated using a checklist, two weeks after using medication through telephone calls and also 4 weeks after the start point during visiting the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children from 6 to 18, Filling the proposed Rome III diagnostic criteria for functional abdominal pain, Having written consent from the parents of these children before their entry to the study Exclusion criteria: Using any kind of psychiatric, antibiotic or probiotic medication in last 2 months, A history of symptoms improvement following 2 weeks of lactose free diet Positive result in lactose respiratory test, Suffering from another digestive disorder or organic disease, in addition to functional abdominal pain, Weight of Height below 5 percentile for appropriate age

Intervention groups

Intervention group: In this group 50 patients who are randomly chosen would receive buspirone. Control group: In this group 50 patients who are randomly chosen would receive placebo.

Main outcome variables

Primary outcome measure treatment response as pain relief in patients using Wong-Baker faces pain rating scale (WBFPRS). Secondary outcome measures the amount of changes in depression severity, anxiety, somatization, sleep quality and clinical impression of severity and improvement from the physician's point of view through The Children's Depression Inventory (CDI), Revised children's manifest anxiety scale TM(RCMASTM), Children's Somatization Inventory-Revised Form (CSI-24), The Sleep Disturbance Scale for Children (SDSC) and Clinical Global Impression Severity and Improvement scales (CGI-S, CGI-I) respectively.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140304016844N3**
Registration date: **2018-01-15, 1396/10/25**
Registration timing: **prospective**

Last update: **2018-01-15, 1396/10/25**
Update count: **0**

Registration date
2018-01-15, 1396/10/25

Registrant information
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Isfahan University of Medical Sicences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-20, 1396/10/30
Expected recruitment end date
2018-04-19, 1397/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of Buspirone and placebo in functional abdominal pain in children

Public title
Comparison of the efficacy of Buspirone and placebo in functional abdominal pain in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children from 6 to 18 Filling the proposed Rome III diagnostic criteria for functional abdominal pain Having written consent from the parents of these children before their entry to the study
Exclusion criteria:
Using any kind of psychiatric, antibiotic or probiotic medication in last 2 months A history of symptoms improvement following 2 weeks of lactose free diet Positive result in lactose respiratory test Suffering from another digestive disorder or organic disease, in addition to functional abdominal pain Weight of Height below 5 percentile for appropriate age
Age
From **6 years** old to **18 years** old
Gender
Both
Phase
3
Groups that have been masked

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

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Buspirone and placebo containing drug bottles will be coded by a pharmacist using random numbers in four blocks (generated by software). Allocation will be concealed and the attending physician, participants, and outcome assessor would be unaware of the drug codes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients, investigators and treating physician and also the person who helps children filling their forms do not know if they are receiving placebo or buspirone.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Islamic Azad University, Najafabad branch
Street address
Islamic Azad University of Najafabad, Najafabad boulevard, Najafabad, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8514143131
Approval date
2017-08-18, 1396/05/27
Ethics committee reference number
15010101951020

Health conditions studied

1

Description of health condition studied
Functional abdominal pain
ICD-10 code
R10.9
ICD-10 code description
Unspecified abdominal pain

Primary outcomes

1

Description
Primary outcome is treatment response as pain relief in patients.
Timepoint
Primary outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
Wong-Baker faces pain rating scale

Secondary outcomes

1

Description
changes in depression severity
Timepoint
This outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
The Children’s Depression Inventory (CDI)

2

Description
changes in anxiety severity
Timepoint
This outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
Revised children’s manifest anxiety scale TM(RCMASTM)

3

Description
changes in somatization severity
Timepoint
This outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
Children’s Somatization Inventory-Revised Form (CSI-24)

4

Description
changes in sleep quality
Timepoint
This outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
The Sleep Disturbance Scale for Children (SDSC)

5

Description
clinical impression of severity from the physician’s point of view
Timepoint
This outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
Clinical Global Impression Severity scale (CGI-S)

6

Description
clinical impression of improvement from the physician’s point of view
Timepoint
This outcome is measured before starting the intervention, 4 weeks after the start point and finally 8 weeks after the end of the intervention.
Method of measurement
Clinical Global Impression Improvement scale (CGI-I)

Intervention groups

1

Description
Intervention group: This group receive buspirone 5 milligrams tablets from Tehran Darou company based on their age and the dosage would increase gradually
Category
Treatment - Drugs

2

Description
Control group: This group receive placebo tablets that are similar to buspirone tablets and in this group also number of using tablets would increase gradually .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Saneian's pediatrics gastroenterology private clinic

Full name of responsible person
Hossein Saneian
Street address
No 310, Qasr intersection, Shamsabadi St, Isfahan
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Isfehan
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Phone
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Omid Yaghini
Street address
Isfahan University of medical sciences, Hezar Jarib St, Azadi square, Isfahan
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yaghini@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Omid Yaghini
Position
Member of Faculty of Medicine/ MD, Pediatrician
Latest degree
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Person responsible for updating data

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Medical doctor
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General Practitioner

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available