

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of Non-Wheat gluten Diet in Children and Adolescents With Functional Abdominal Pain

Protocol summary

Study aim

Investigating the effect of wheat / gluten-free diet on gastrointestinal and non-gastrointestinal symptoms in children and adolescents with functional abdominal pain

Design

Randomized clinical trial Phase 1 on 60 patients with functional abdominal pain that divided into 2 groups by random numbers table

Settings and conduct

Children with functional abdominal pain based on Rome 4 criteria of 2 to 18 years old, in 1398-1399 enter the study. Randomly, they are divided into two groups. Control (initiation of gluten-containing diet intervention) and intervention group (initiation of gluten-free diet intervention). At the beginning and at the end of each intervention and at the end of the wash out phase, gastrointestinal and non-gastrointestinal symptoms are recorded by the researcher by checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with functional abdominal pain according to the criteria of Roman four aged 12 to 18 years. Non-entry Criteria: Children with abdominal pain with organic causes.

Intervention groups

Children with functional abdominal pain between the ages of 12 and 18 are divided into two groups based on a table of random numbers. The case group is given a gluten-free diet for 3 weeks. Then 3 weeks of regular diet as a wash out period and then 3 weeks of gluten-containing diet. The control group is first given a gluten-free diet for 3 weeks, then a regular diet for 3 weeks, and then a gluten-free diet for 3 weeks.

Main outcome variables

abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043224N2**

Registration date: **2020-06-09, 1399/03/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-09, 1399/03/20**

Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name

Peiman Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6331

Email address

peiman.nasri@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Non-Wheat gluten Diet in Children and Adolescents With Functional Abdominal Pain

Public title

Evaluation of Non-Wheat gluten Diet in Children and Adolescents With Functional Abdominal Pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children with functional abdominal pain according to the criteria of Rome 4 in the ages of 12 to 18 years, referred to the subspecialty gastroenterology clinics of Isfahan University of Medical Sciences with the conditions..
 Do not take steroids or nonsteroidal anti-inflammatory drugs or any other medication for 2 weeks before endoscopic examination Patients who are not on medication (Do not take steroids / antacids / proton pump inhibitors / probiotics / nonsteroidal anti-inflammatory drugs / antidepressants and antipsychotics) Patients who have not been on a gluten-free / gluten-free diet for the past 6 months Lack of sensitivity to wheat Absence of other organic diseases of the gastrointestinal tract (celiac disease, inflammatory bowel disease)
 Absence of abdominal surgery (intestinal resection)
 Absence of diseases, infectious / diabetes mellitus / systemic autoimmune / immunodeficiency / psychological disorders No previous anaphylactic reaction attacks Negative Anti endomysial Ab test
Exclusion criteria:
 Children with abdominal pain with organic causes.

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Each child with functional abdominal pain is placed in the intervention or control group using a random number table as soon as the doctor diagnoses it. In this way, the even members are in the intervention group and the odd members are in the control group. This process continues until the sample size is complete.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Isfahan University of Medical Sciences
Street address
 Ethics committee of Isfahan University of Medical Sciences, Isfahan University of medical sciences, Hezarjarib Ave,
City
 Isfahan
Province
 Isfahan
Postal code
 ۷۳۴۶۱-۸۱۷۴۶

Approval date
2019-04-12, 1398/01/23

Ethics committee reference number
IR.MUI.MED.REC.1398.584

Health conditions studied

1

Description of health condition studied
Functional abdominal pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Functional abdominal pain

Timepoint
In both groups before the intervention and three weeks after the intervention and three weeks after the Wash out.

Method of measurement
Check list and questionnaire

Secondary outcomes

1

Description
In each stage of filling out the checklist, "In addition to abdominal pain, variables of diarrhea, bloating, body pain, limb pain, anxiety, headache, and feeling unwell are also evaluated."

Timepoint
In both groups before the intervention and three weeks after the intervention and three weeks after Wash out.

Method of measurement
Checklist and questionnaire.

Intervention groups

1

Description

Intervention group: First, a gluten-free diet is given for 3 weeks. Then 3 weeks of regular diet as a wash out period and then 3 weeks of gluten-containing diet.

Category

Treatment - Other

2

Description

Control group: First, a gluten-free diet is given for 3 weeks, then a normal diet for 3 weeks, and then a gluten-free diet for 3 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Children's Hospital

Full name of responsible person

Nasri Peiman

Street address

Imam Hosein Children's Hospital, Imam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Haghjoo Shaghayegh Dr

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Research and Technology Deputy of Medical Sciences, Hezar Jerib Avenue, Isfahan

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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

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

Peiman Nasri

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology, Hepatology and Nutrition

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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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

Data about main outcome

When the data will become available and for how long

6 months after publication

To whom data/document is available

Everybody

Under which criteria data/document could be used

For research and clinical practice

From where data/document is obtainable

peiman94157@gmail.com

What processes are involved for a request to access data/document

Please contact me via Email address. I will send you the data after one week.

Comments