

# 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

#### City

Isfahan

#### Province

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#### Phone

+98 31 3386 9141

#### Email

peiman94157@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Haghjoo Shaghayegh Dr

#### Street address

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

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#### Postal code

8174673461

#### Phone

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#### Email

research@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

Peiman Nasri

#### Position

Assistant professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gastroenterology, Hepatology and Nutrition

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## Person responsible for scientific inquiries

### Contact

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#### Latest degree

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#### Other areas of specialty/work

Pediatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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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

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