

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of the effects of Zizyphus Jujuba Fruit's product and Pidrolax in the Childhood Functional Constipation which referred to Rasool Akram Clinic: a randomized clinical trial

#### Protocol summary

##### Study aim

Determination of the effect of Zizyphus Jujuba Fruit's product compared to standard product in pediatric functional constipation

##### Design

Based on the statistical studies, sample size will be 110 people. They will use jujube extracts and PEG in two groups which be allocated by random blocked randomization. Treatment will take 4 weeks. and we will ask them by phone or verbal about effects in the end of 1,2,4 weeks.

##### Settings and conduct

This study is a randomized controlled clinical trial among patients referring to pediatric gastroenterology clinic of Rasool Akram Hospital.

##### Participants/Inclusion and exclusion criteria

1 - Children 2 to 12 years of age of both sexes who have been diagnosed with functional constipation based on ROMEIV criteria. 2. Absence of diseases such as: chronic and significant psychiatric disorders; - mental retardation; - history of chronic diseases; - history of developmental disorders in infancy and childhood; - moderate to severe traumatic history; - Chronic gastrointestinal disorders and congenital anomalies in the digestive tract - history of gastrointestinal surgery - IBS diagnosis based on ROMEIV criteria 3. Absence of chronic drug use history and medical treatment that has an effect on GI movement 4. no history of death or parental separation. 5. absence of symptoms of organic constipation 6. Fecal impaction in the physical examination, which can not be eliminated.

##### Intervention groups

Children aged 2-12 years with functional constipation with nutritional and behavioral instructions and PEG daily 0.4gr / kg Jujuba Fruit's product 0.5cc/kg BD

##### Main outcome variables

number of defecation per week Consistency of stool

Number of incontinence times Painless defecation  
Satisfaction of the drug Possible complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171213037866N1**

Registration date: **2018-05-03, 1397/02/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-03, 1397/02/13**

Update count: **0**

##### Registration date

2018-05-03, 1397/02/13

##### Registrant information

##### Name

Nasim Behnoud

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4469 0358

##### Email address

behnoud.n@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2018-07-23, 1397/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effects of Zizyphus Jujuba Fruit's product and Pidrolax in the Childhood Functional Constipation which referred to Rasoul Akram Clinic: a randomized clinical trial

**Public title**  
Effects of Zizyphus Jujuba Fruit's product in the Childhood Functional Constipation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age between 2-12 years old and presence of Functional Constipation based on ROME IV  
**Exclusion criteria:**  
Any symptom of organic constipation in the history, physical examination or para clinics (such as hypothyroidism, Hirschsprung disease, chronic intestinal pseudo-obstruction) and the presence of other chronic diseases that lead to long-term use of drugs and long-term consumption of any drug that can cause constipation.

**Age**  
From **2 years** old to **12 years** old

**Gender**  
Both

**Phase**  
1

**Groups that have been masked**

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **110**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be randomly assigned to intervention and control groups based on a randomized block method.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Research Committee of Iran University of Medical Sciences  
**Street address**  
Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۳۹۶۱۴۵۳۵  
**Approval date**  
2018-02-25, 1396/12/06  
**Ethics committee reference number**  
IR.IUMS.REC 1396.9421309003

## Health conditions studied

**1**

**Description of health condition studied**  
Pediatric functional constipation  
**ICD-10 code**  
K59.0  
**ICD-10 code description**  
Constipation

## Primary outcomes

**1**

**Description**  
Frequency of defecation per week  
**Timepoint**  
Before intervention, 1, 2, 3, 4 weeks after starting treatment  
**Method of measurement**  
Standard questionnaire

**2**

**Description**  
The frequency of hard stool in a week  
**Timepoint**  
Before intervention, 1, 2, 3, 4 weeks after starting treatment  
**Method of measurement**  
Standard questionnaire

**3**

**Description**  
Frequency of fecal incontinence per week  
**Timepoint**  
Before intervention, 1, 2, 3, 4 weeks after starting treatment  
**Method of measurement**  
Standard questionnaire

#### 4

**Description**

The frequency of painful defecation in the week

**Timepoint**

Before intervention, 1, 2, 3, 4 weeks after starting treatment

**Method of measurement**

Standard questionnaire

#### 5

**Description**

Frequency of drug adoption by the child per week

**Timepoint**

Before intervention, 1, 2, 3, 4 weeks after starting treatment

**Method of measurement**

Standard questionnaire

#### 6

**Description**

The frequency of side effects in weeks

**Timepoint**

Before intervention, 1, 2, 3, 4 weeks after starting treatment

**Method of measurement**

Standard questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Control group: Nutritional and behavioral commands and PEG daily 0.4gr / kg

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: Nutritional and behavioral commands and Zizyphus Jujuba Fruit's product

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

درمانگاه بیمارستان رسول اکرم

**Full name of responsible person**

نسیم بهنود

**Street address**

تهران - ستارخان - خ. نیایش - نبش خیابان منصوری - بیمارستان

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### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Kazem Malakouty

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Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences

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1449614535

**Phone**

+98 21 86701

**Email**

admins@iums.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Nasim Behnoud

**Position**

Student in Iranian Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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**Name of organization / entity**

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**Full name of responsible person**

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**Fax**

**Email**

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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