

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)

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Email address

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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
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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

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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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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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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