Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of tht effects of Zizyphus Jujuba Fruit’s product and Pidrolax in the Childhood Functional Constipation which referred to Rasoul Akram Clinic: a ra ndomized 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 defication per week Consistency of stool Number of incontinence times Painless defication 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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+98 21 4469 0358

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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 tht effects of Zizyphus Jujuba Fruit’s product and Pidrolax in the Childhood Functional Constipation which referred to Rasoul Akram Clinic: a ra ndomized 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

۱۴۴۹۶۱۴۵۳۵

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 حضرت رسول اکرم (ص)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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