

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison the effects of syrup of Zyzyphus jujube and Pidrolax Glycol in treatment of 2-10 years Children with Functional Constipation referred to 17-Shahrivar Hospital; A double-blind randomized clinical trial

Protocol summary

Study aim

Comparison of Ziziphus jujuba Mill. syrup with pidrolax (Polyethylene Glycol)

Design

Double Blinded clinical trial

Settings and conduct

This study will be done because of no certain treatment for functional constipation in children. It will be held on pediatric clinic in 17-shahrivar hospital in Rasht as a double blinded clinical trial study. blinding will be done for both physician and patient toward type of prescribing drugs.

Participants/Inclusion and exclusion criteria

children between 2-10 years old will be included in the study participants with hirschsprung disease, spina bifida occulta, cystic fibrosis, neurological abnormality, congenital anal disorders, Ogilvie syndrome, celiac disease, hypothyroidism, Diabetes insipidus, history of colorectal surgery, existence of fissure and no consent of parent for participation, will not included in the study

Intervention groups

Ziziphus jujuba mill syrup group, Pidrolax group

Main outcome variables

Visual Analogue Scale and pediatric functional constipation scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131006014915N3**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **prospective**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name

Amin Saeidinia

Name of organization / entity

Medicinal plants research center of student Basij, Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of syrup of Zyzyphus jujube and Pidrolax Glycol in treatment of 2-10 years Children with Functional Constipation referred to 17-Shahrivar Hospital; A double-blind randomized clinical trial

Public title

evaluation of Zyzyphus jujuba syrup in treatment of functional constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

functional constipation age between 2-10 years

Exclusion criteria:

Hirschsprung disease spina bifida occulta cystic fibrosis
 neurologic disorder anal congenital disorders ogilvie
 disease celiac disease Hypothyroidism diabetes insipidus
 history of colorectal surgery fissure no consent of
 patients

AgeFrom **2 years** old to **10 years** old**Gender**

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Blinding is two-sided. it means that both physician and
 patient will be blind toward drug type. for this purpose,
 trained nurse is aware of randomization but physician
 and patient are blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی گیلان

Street address

Namjoo street

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

functional constipation

ICD-10 code

K59.9. Fun

ICD-10 code description

K59.0. Constipation

Primary outcomes**1****Description**

Visual Analogue Scale

Timepointin the starting day of study (before intervention), 1 and 2
months after starting drugs**Method of measurement**

by using ruler of pain determination between 0 to 10

Secondary outcomes**1****Description**

pediatric functional constipation scale

Timepointin the starting day of study (before intervention), 1 and 2
months after starting drugs**Method of measurement**

weak, moderate, good

Intervention groups**1****Description**First Intervention group: Oral consumption of ziziphus
jujuba syrup prepared by pharmacist, 1-2 cc/day for two
months**Category**

Treatment - Drugs

2**Description**Second Intervention group: Oral consumption of syrup
prepared by Pidrolax powder, 1 cc/kg one time per day**Category**

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

17-shahrivar hospital

Full name of responsible person

Shohreh Maleknejad

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pediatric department, 17-shahrivar hospital, Namjoo street

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<http://www.gums.ac.ir/17shahrivar>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

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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

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

fateme keihanian

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Latest degree

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Web page address**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

No - There is not 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

Not applicable

Title and more details about the data/document

Main outcomes of the study will be shared as an article
after blinding participants' information

When the data will become available and for how long

Initiation of access to data will be at 6 months after
publication of the work

To whom data/document is available

Scientific and academic researchers

Under which criteria data/document could be used

access to data will be only for result evaluation for target
journal in publication process and only published findings
in the article will be accessed to other researchers

From where data/document is obtainable

correspondence author of the study

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

Sending request to corresponding author's email and if
confirmed, sending the requested information will be
done

Comments