

# 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)

###### Phone

+98 13 1669 0099

###### Email address

a.saeidynia@yahoo.com

##### 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

**Age**From **2 years** old to **10 years** old**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**Target 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

**Timepoint**in 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

**Timepoint**in 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

**Street address**

pediatric department, 17-shahrivar hospital, Namjoo street

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**Web page address**

<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**

Shohreh Maleknejad

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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

**Street address**

First Floor, Medical Faculty, Guilan University, 5th Kilometer of Tehran road, Rasht

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**Full name of responsible person**

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**Fax****Email**

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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**