Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative evaluation between the laxa plus barij and Polyethylene glycol (4000) in the pediatric functional constipation in chidren 2 to 15 years old

Protocol summary

Study aim
Determination and comparison of the effect of Laxaplus and Polyethylene Glycol powder 4000 in the treatment of constipation in patients 2 to 15 years old

Design
A simple randomized clinical trial (not blinded) using simple random table (phase 3), with control group (parallel groups) that 60 patients with functional constipation are randomly allocated to 2 groups (Intervention and control groups).

Settings and conduct
60 patients aged 2 to 15 years old referred to Imam Hossein Hospital, whose functional constipation was confirmed by Rome 4 criteria, (after obtaining written consent) are randomly allocated to 2 groups (receiving Laxaplus 1 cc/kg daily divided in 3 times, in the children with body weight less than 30 kg and 10 cc 3 times daily, in body weight more than 30 kg orally half an hour before meals and receiving PEG (4000) Powder 0.7 gr/kg 3 times daily). Both groups will be evaluated for 8 weeks after intervention. (Not blinded)

Participants/Inclusion and exclusion criteria
Inclusion criteria: Functional constipation confirmed by ROME 4 criteria; Exclusion criteria: Patients with stractural causes of constipation; chronic illness who need special care; History of the gastrointestinal tract surgery except for appendectomy; allergy or drug sensitivity; Autism and major psychotic disorders;Using some drugs; Weight loss more than 5 percent in the past 3 months; Using drugs that have an unknown effect on the GI tract.

Intervention groups
Intervention group: Laxaplus 1cc/kg daily divided in 3 times , in the children with body weight less than 30 kg and 10 cc 3 times daily, in the children with body weight more than 30 kg orally half an hour before meals for 8 weeks; Control group: PEG(4000)Powder 0.7 g /kg orally 3 times daily for 8 weeks.

Main outcome variables
Constipation improvement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190410043224N3**
Registration date: **2020-06-21, 1399/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-21, 1399/04/01**
Update count: **0**

Registration date
2020-06-21, 1399/04/01

Registrant information

Name
Peiman Nasri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3261 6331

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peiman.nasri@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative evaluation between the laxa plus barij and Polyethylene glycol (4000) in the pediatric functional constipation in chidren 2 to 15 years old

Public title
Comparison between the laxa plus barij and Polyethylene glycol in the pediatric constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Functional constipation confirmed by ROME 4 criteria Defecation twice a week or less; History of stool retention; history of painful defecation; History of large stool diameter; History of large stool mass in rectum;
Exclusion criteria:
Patients with structural causes of constipation such as celiac disease; pseudo-obstruction; hypothyroidism; spina bifida, anorectal malformation; hirschsprung's disease; Patients with chronic illness who need special care such as: renal stone; sickle cell anemia; cerebral palsy; hepatitis; hematologic diseases; gastrointestinal bleeding; recurrent fever or fever without locolized sign; Pregnanccy; History of gastrointestinal tract surgery exept for appendectomy; History of allergy or Drug sensitivity; autism; major psychotic disorder such as bipolar disorder; schizophrenia; Children who had experienced physical abuse and sexual abuse; Use of medication such as Metoclopramide, Erythromycin, Bethanechol, CoAmoxiclav, Azithromycin, Domperidone, Amitriptyline, Hyoscyamine, Clonidine, Baclofen, Dicyclomine, Scopolamine; Weight loss more than five percent in the past three monthes; Using drugs that have an unknown effect on the gastrointestinal tract
Age
From **2 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples are selected among the target community according to the entry and exit criteria by convenience non probability method ,then they are randomly allocated into intervention and control groups by Random allocation software developed by Dr.Mahmoud Saghaei.
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
Ethics committee of Esfahan University of Medical Sciences
Street address
Imam Khomeini/ children hospital Imam hossein
City
Esfahan
Province
Isfehan
Postal code
8195163381
Approval date
2020-04-27, 1399/02/08
Ethics committee reference number
IR.MUI.MED.REC.1399.082

Health conditions studied

1

Description of health condition studied
Functional constipation
ICD-10 code
K59.09
ICD-10 code description
Other constipation

Primary outcomes

1

Description
Constipation improvement
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Clinical Examination; Questionnaire of Constipation Evaluation

Secondary outcomes

1

Description
Treatment side effects
Timepoint

During the study and 8 weeks after the intervention

Method of measurement

Clinical Examination; Questionnaire of Constipation Evaluation

Intervention groups

1

Description

Intervention group: Laxa plus barij 1cc/kg daily divided in 3 times ,in the children with body weight less than 30 kg and 10cc 3 times daily,in the children with body weight more than 30 kg orally half an hour before meals for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Polyethylene glycol (4000) Powder (Sepidaj Pharmaceutical Company) 0.7 g / kg orally three times daily for eight weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Children's Hospital

Full name of responsible person

Nasri Peiman

Street address

Imam Hosein Children's Hospital, Imam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

Research and Technology Deputy of Medical Sciences, Hezar Jerib Avenue, Isfahan

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8174673461

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Barij Medicinal Plant Research Center

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shima Saeidi

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
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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