Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative evaluation between the Golghand majun (Rosa damascena) and Polyethylene glycol (4000) in the pediatric functional constipation in chidren 2 to 15 years old referred to Emam Hossein hospital in 2019-2020

Protocol summary

Study aim

Determination and comparison of the effect of Golghand majun and Polyethylene Glycol powder 4000 in the treatment of constipation in patients referred to Imam Hossein Hospital in 2019-2020.

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 two groups (Intervention and control groups).

Settings and conduct

Sixty patients aged 2 to 15 years referred to Imam Hossein Hospital, whose functional constipation was confirmed by Cryitria Roman 4, (after obtaining written consent) are randomly allocated to two groups (receiving Golghand majun 500 mg / kg three times daily and receiving Polyethylene glycol (4000) Powder 0.7 g / kg three 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 ROMAN criteria 4; Stool elimination twice a week or less; History of stool retention; Stiff or painful intestinal function; History of large stool diameter; History of large stool mass in rectum Exclusion criteria:Patients with causes of organic constipation; Patients with chronic illness who need special care; Pregnanccy; History of surgery involvig the gastrointestinal tract exept for appendectomy; History of allergies or drug allergies; Diagnosis of autism and major psychosis disorder; Use of some drugs; Weight loss over five percent in the past three months; Use of drugs that have an unknown delay in the gastrointestinal tract

Intervention groups

Intervention group: Golghand majun 500 mg / kg divided in three times daily, orally half an hour before meals for eight weeks Control group: Polyethylene glycol (4000) Powder 0.7 g / kg orally three times daily for eight weeks

Main outcome variables

Constipation improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043224N1**
Registration date: **2020-02-20, 1398/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-20, 1398/12/01**
Update count: **0**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name

Peiman Nasri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation between the Golghand majun (Rosa damascena) and Polyethylene glycol (4000) in the pediatric functional constipation in chidren 2 to 15 years old referred to Emam Hossein hospital in 2019-2020

Public title

Comparison between the Golghand majun and Polyethylene glycol in the pediatric constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Functional constipation confirmed by ROMAN criteria 4 Stool elimination twice a week or less History of stool retention Stiff or painful intestinal function History of large stool diameter History of large stool mass in rectum

Exclusion criteria:

Patients with causes of organic constipation such as celiac disease, pseudo-obstruction, hypothyroidism, spinabifida, anorectal malformation, hirschsprung's disease Patients with chronic illness who need special care such as: stone kidney, sickle cell anemia, cereberal palsy, hepatitis, hematologic diseases, gastrointestinal bleeding, relapse fever or fever without locolized sign Pregnanccy History of surgery involvig the gastrointestinal tract exept for appendectomy History of allergies or drug allergies Diagnosis of autism, major psychosis disorder such as bipolar disorder, schizophrenia, children who have experienced physical abuse and sexual abuse Use of medication such as Metoclopyramide, Erythromycin, Butanol, Amoxiclav, Azithromycin, Domperidone, Amitriptyline, Hyoscyamine, Clonidine, Baclofen, Dicyclomine, Scopolamine Weight loss over five percent in the past three monthes Use of drugs that have an unknown delay in 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

Patients were randomly divided into intervention and control groups using simple random number table (individual and simple randomization). The intervention group was allocated to the treatment of the Golghand majun and the control group was allocated to the proven treatment of constipation (administration of Polyethylene glycol powder).

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

Isfahan University of Medical Sciences

Street address

Research and Technology Deputy of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan

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Province

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8174673461

Approval date

2019-09-15, 1398/06/24

Ethics committee reference number

IR.MUI.MED.REC.1398.330

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
Golghand majun (Barij Pharmaceutical Company) 500 mg / kg divided in three times daily, orally half an hour before meals for eight 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 Hossein Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Academic

Person responsible for general inquiries

Contact
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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