

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative evaluation between the Golghand majun (*Rosa damascena*) and Polyethylene glycol (4000) in the pediatric functional constipation in children 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; Pregnancyy; History of surgery involvig the gastrointestinal tract except 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

Country

Iran (Islamic Republic of)

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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 children 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 ROME 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, cerebral palsy, hepatitis, hematologic diseases, gastrointestinal bleeding, relapse fever or fever without localized sign
Pregnancy
History of surgery involving the gastrointestinal tract except 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 Metoclopramide, Erythromycin, Butanol, Amoxiclav, Azithromycin, Domperidone, Amitriptyline, Hyoscyamine, Clonidine, Baclofen, Dicyclomine, Scopolamine
Weight loss over five percent in the past three months
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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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

Dr. Mehrdad Memarzadeh

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Imam Hossein Hospital, Imam Khomeini Avenue, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saeedeh Ghaedi

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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