Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison between Cassia Fistula syrup and Poly ethylen glycol in children with functional constipation

Protocol summary

Summary

Cassia Fistula is a medical plant. Its fruit's pulp have been claimed to be effective as a laxative. Previously, we conducted a randomized, placebo-controlled clinical trial in 81 children with functional constipation and compared cassia fistula with Mineral oil within 3 weeks medication. In this study we want to conduct another research in 100 children of both sexes, aged 2-15 years old, with diagnosed Functional Constipation according to the Rome Ⅲ criteria. they will be randomized into 2 equal groups of 50. 1 g/kg/d Poly Ethylen Glycol (pydrolax) were given in one group and 0.15 g/Kg of aqueous extract of Cassia fistula's fruit's pulp (in form of syrup), daily in another group, for 4 weeks. Number of defecation in the toilet per week, intensity of pain during defecation, and stiffness of stool (by Visual Analog Scale) will be compared between groups after 4 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303196932N2**
Registration date: **2013-12-04, 1392/09/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-04, 1392/09/13

Registrant information

Name

Seyyed Ali Mozaffarpur

Name of organization / entity

Babol University of Medical Scienses

Country

Iran (Islamic Republic of)

Phone

+98 11 1219 9936

Email address

seyyedali1357@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Cassia Fistula syrup and Poly ethylen glycol in children with functional constipation

Public title

The effect of Cassia Fistula in pediatric constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children between 2 to 15 years old who have at least 2 or more of the followings: Less than 2 defections in the toilet each week: More than 1 episode of fecal incontinence per week; History of retentive posturing or excessive volitional stool retention; History of painful or hard bowel movements; Presence of a large fecal mass in the rectum; History of large diameter stools that may obstruct the toilet; children with inclusion criteria will be seen by a pediatric gastroenterologist to provide complete functional constipation criteria. If the history and physical examination, functional constipation is not proved or questioned, anorectal manometry is

performed.If confirmed in functional constipation and the tendency of parents, children are enrolled. Exclusion criteria: any symptom of organic constipation in the history or physical examination; any evidence of organic constipation in anorectal manometry; fecal impaction on physical examination that cannot be removed; presence of other chronic diseases that lead to long-term use of drugs; Long-term consumption of drugs that can cause constipation; intolerance of drinking cassia syrup (nausea and vomiting or severe abdominal pain or allergic symptoms); no compliance, the patient's unwillingness to continue treatment; If any complication due to drugs (such as crampy abdominal pain; probable electrolyte disorder signs due to severe diarrhea (potassium imbalance); muscle weakness or palpitation;and facial and limbs edema; or other complications that are possibly related to drugs) happen, the treatment will be discontinued the adverse effect are recorded.

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Babol University of Medical Sciences

Street address
Babol University of Medical Sciences

City
Babol

Postal code

Approval date
2013-11-09, 1392/08/18

Ethics committee reference number
30/3326/ژ/پ

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation (atonic) (simple) (spastic)

Primary outcomes

1

Description
Number of defications per week

Timepoint
before intervention and 7, 14, 21 ,28 days after begining of the intervention

Method of measurement
questionairre

2

Description
Intensity of pain of defication

Timepoint
before intervention and 7, 14, 21,28 days after begining of the intervention

Method of measurement
questionairre and VAS

3

Description
Intensity of stiffness of the stool in defication

Timepoint
before intervention and 7, 14, 21,28 days after begining of the intervention

Method of measurement
questionairre and VAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aqueous extract of Cassia fistula’s fruit’s pulp (in form of syrup), 0.15 g/Kg/day, orally, divided in 2 or 3 separated dose, after meals, for 28 days

Category
Treatment - Drugs

2

Description
Control group:PEG, 1 gr/kg/day, orally, divided in 2

separated dose, after meals, for 28 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Non-Communicable Pediatric Diseases Research Center, Amirkola children's hospital

Full name of responsible person

Mohaddese Mirzapour

Street address

Non-Communicable Pediatric Diseases Research Center, No 19, Amirkola children's hospital, Amirkola.

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Amrollah Mostafazade

Street address

Babol University of Medical Sciences, Deputy of Research and Technology

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyyed Ali Mozaffarpur

Position

PHD of traditional medicine / Head of the faculty of Traditional Medicine

Other areas of specialty/work

Street address

faculty of traditional medicine, Babol University of Medical Sciences

City

Babol

Postal code

Phone

+98 11 1324 6963

Fax

Email

seyyedali1357@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyyed Ali Mozaffarpur

Position

PHD of traditional medicine

Other areas of specialty/work

Street address

traditional medicine department, Babol University of Medical Sciences

City

Babol

Postal code

Phone

+98 11 1324 6963

Fax

Email

seyyedali1357@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyyed Ali Mozaffarpur

Position

PHD of traditional medicine / Head of the faculty of Traditional Medicine

Other areas of specialty/work

Street address

faculty of traditional medicine,Babol University of Medical Sciences

City

Babol

Postal code

Phone

+98 11 1324 6693

Fax

Email

seyyedali1357@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty