Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Determination the efficacy of Cassia Fistula in management of pediatric functional constipation

Protocol summary

Summary

Cassia Fistula is a medical plant. Its fruit's pulp have been claimed to be effective as a laxative. A randomized, case-controlled clinical trial will be conducted to investigate this matter. A total of 72 children of both sexes, aged 4-13 years old, with diagnosed Functional Constipation according to the Rome Ⅲ criteria will be randomized into 2 equal groups of 36 each to receive either 1-4 teaspoons mineral oil or 0.15 g/Kg of aqueous extract of Cassia fistula's fruit's pulp (in form of syrup), daily, for three 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 3 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107026932N1**
Registration date: **2011-08-22, 1390/05/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-08-22, 1390/05/31

Registrant information

Name

Seyyed Ali Mozaffarpur

Name of organization / entity

Babol University of Medical Scienses

Country

Iran (Islamic Republic of)

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+98 11 1219 9936

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seyyedali1357@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University (Faculty of Medical Sciences)

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination the efficacy of Cassia Fistula in management of pediatric functional constipation

Public title

Efficacy of Cassia Fistula in constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children between 4 to 13 years old who have at least 2 or more of the followings: Less than 2 defecations 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 are visited by pediatric gastroentrologist to provide complete functional constipation criteria. If the history and physical examination or question is not for functional constipation, ano-rectal manometry is performed 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, Note: 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 **4 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

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
Shahed University

Street address
Shahed University, Opposite the shrine of Imam Khomeini (RA), Qom Highway beginning, Tehran

City
Thran

Postal code
3319118651

Approval date
2011-05-31, 1390/03/10

Ethics committee reference number
112251/4

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Number of defications per week

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

Method of measurement
questionairre

2

Description
Intensity of stiffness of the stool in defication

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

Method of measurement
questionairre and VAS

3

Description
Intensity of pain of defication

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

Method of measurement
questionairre and VAS

Secondary outcomes

1

Description
frequency of fecal incontinence per week

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

Method of measurement
questionaire

2

Description
frequency of fecal soiling per week

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

Method of measurement
questionairre

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 21 days
Category
Treatment - Drugs

2

Description
Control group: Mineral oil, 1-4 teaspoons, orally, divided in 2 or 3 separated dose, after meals, for 21 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola's Children's Specialized Hospital, Babol University of Medical Sciences
Full name of responsible person
Seyyed Ali Mozaffarpur
Street address
Children's Specialized Hospital-Amirkola-Babol
City
Babol

2

Recruitment center
Name of recruitment center
Dr. Esmaeili's office (Pediatric gastroenterologist and professor of Thesis)
Full name of responsible person
Seyyed Ali Mozaffarpur
Street address
upper floor Pasteur Laboratory-
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University - Faculty of Medical Sciences
Full name of responsible person
Dr. Mohsen Naseri
Street address
Shahed University-opposite the shrine of Imam Khomeini (RA)-Qom Highway beginning -Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University - Faculty 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
Full name of responsible person
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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