

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

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

#### Protocol summary

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#### 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.

#### 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

#### 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 Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 11 1219 9936

#### Email address

#### 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 gastroenterologist 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 defecations per week

##### Timepoint

before intervention and 7, 14, 21 days after beginning of the intervention

##### Method of measurement

questionairre

#### 2

##### Description

Intensity of stiffness of the stool in defecation

##### Timepoint

before intervention and 7, 14, 21 days after beginning of the intervention

##### Method of measurement

questionairre and VAS

#### 3

##### Description

Intensity of pain of defecation

##### Timepoint

before intervention and 7, 14, 21 days after beginning 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 beginning of the intervention

##### Method of measurement

questionaire

#### 2

##### Description

frequency of fecal soiling per week

##### Timepoint

before intervention and 7, 14, 21 days after beginning 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

Seyyed Ali Mozaffarpur

##### Position

Student of PhD of Traditional Medicine

##### Other areas of specialty/work

##### Street address

Group of

##### City

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahed University- Faculty of Medical Sciences-Group of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Naseri

##### Position

Pharmacologist(MD.PhD)-Associate Professor at the Shahed University

##### Other areas of specialty/work

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"Salamat" clinic- besides "Mostafa Khomeini" hospital- "Italia" Avenue- Tehran-

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Student of PhD of Traditional Medicine

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**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*