

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effect of Cassia Fistula syrup in geriatrics constipation in comparison with the lactulose

#### Protocol summary

##### Study aim

Evaluation of Cassia Fistula syrup compared to lactulose syrup in improving constipation in the elderly

##### Design

A double-blind randomized clinical trial study is performed with a control group. 70 elderly patients referred to the gastrointestinal clinic of Ayatollah Rouhani Hospital in Babol with the diagnosis of constipation, randomly assigned to two groups of cassia fistula and lactulose, and are followed for two weeks.

##### Settings and conduct

Elderly patients referred to the gastroenterology clinic of Ayatollah Rouhani Hospital in Babol after the diagnosis of constipation based on the Rome IV checklist are included in the study. Patients in two parallel groups are followed for two weeks and the information is recorded in the questionnaire. Patients and evaluators are blind to the study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age over 60 years 2- Diagnosis of constipation based on ROME IV criteria Exclusion criteria: 1. The presence of organic diseases is the basis for constipation 2. Presence of cardiovascular, neurological, metabolic, Hematologic or mental disorders or malignancy

##### Intervention groups

Intervention group: Cassia fistula syrup in 250 cc containers, 30 ccs daily (in three separate doses) is given to patients for two weeks. Control group: Lactulose syrup in 250 cc containers, 30 ccs daily (in three separate doses) is given to patients for two weeks.

##### Main outcome variables

Frequency of defecation, Feeling of incomplete emptying after defecation, Number of times to use the manual maneuver, Stiffness of stools

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200105046009N3**

Registration date: **2020-07-17, 1399/04/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-07-17, 1399/04/27**

Update count: **0**

##### Registration date

2020-07-17, 1399/04/27

##### Registrant information

##### Name

Seyyed Ali Mozaffarpur

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 4728

##### Email address

dr.mozaffarpur@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-22, 1399/04/02

##### Expected recruitment end date

2020-10-23, 1399/08/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Cassia Fistula syrup in geriatrics constipation in comparison with the lactulose

**Public title**

The effect of Cassia Fistula syrup in geriatrics constipation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 60 years Diagnosis of constipation based on ROME IV criteria

**Exclusion criteria:**

The presence of organic diseases is the basis for constipation Presence of cardiovascular disease, neurological disease, metabolic disease or mental disorders. Hematologic disease or malignant tumor (unless recurrent in the last 5 years) History of alcohol use or substance abuse

**Age**

From **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The size of the blocks is 4. Drugs in two categories (drug and standard treatment) are poured into identical containers by the study pharmacist and sent to the study statistics specialist. The statistician encodes them and places them in blocks of 4 (containing 2 numbers from each group). And is given to the researcher in blind form. Unlock codes will be done after reading. In case of side effects, the drug code will be unlocked.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Lactulose and Floss syrup in a single form, with the same label, will be prepared by a pharmacist in the Medicinal Plants Laboratory of the Faculty of Iranian Medicine, Babol University of Medical Sciences. The only person who knows the nature of the syrups is the pharmacist involved in the project. Due to the fact that the consistency and shape of the drugs are different, it is not possible to blind the patient in this regard. Therefore, the study will be done one-way blind (evaluator blinding)

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study, a total of 70 patients will be admitted and patients will be randomly divided into two groups. The

first group are patients who receive floss syrup and the second group are patients who receive lactulose syrup. The data required for this study will also be collected through questionnaires 1 to 6.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Approval date**

2020-06-28, 1399/04/08

**Ethics committee reference number**

IR.MUBABOL.HRI.REC.1399.116

**Health conditions studied****1****Description of health condition studied**

geriatrics constipation

**ICD-10 code**

K59.0

**ICD-10 code description**

Constipation

**Primary outcomes****1****Description**

Frequency of defecation

**Timepoint**

Number per week

**Method of measurement**

counting and recording the number of defecation per week

**Secondary outcomes****1****Description**

Feeling of incomplete emptying after defecation

**Timepoint**

Before intervention and 7 and 14 days after intervention

**Method of measurement**

Daily questionnaire on quality of defecation

**2****Description**

Number of times of manual maneuver in defecation

**Timepoint**

Before intervention and 7 and 14 days after intervention

**Method of measurement**

Daily questionnaire on quality of defecation

**3****Description**

Stiffness of stool

**Timepoint**

Before intervention and 7 and 14 days after intervention

**Method of measurement**

Visual Analogue Scale

**4****Description**

Quality of Life

**Timepoint**

Before intervention and 14 days after intervention

**Method of measurement**

Patient Assessment of Constipation Quality of Life Questionnaire (the Persian Version)

**Intervention groups****1****Description**

Intervention group: Cassia fistula syrup prepared and standardized in the Laboratory of Medicinal Plants of Babol School of Traditional Medicine, 30 cc daily (in three separate doses) for 14 days for the elderly with constipation and on days 0 (before Drug initiation), 7 and 14 are evaluated.

**Category**

Treatment - Drugs

**2****Description**

Control group: Lactulose syrup (made by Exir Company), 30 cc daily (in three separate doses) for 14 days for the elderly with constipation and on days 0 (before Drug initiation), 7 and 14 are evaluated.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Roohani Hospital

**Full name of responsible person**

Seyyed Ali Mozaffarpur

**Street address**

Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3219 4730

**Email**

seyyedali1357@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

**Street address**

Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3219 4730

**Email**

seyyedali1357@gmail.com

**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**

Public

**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**

Babol University of Medical Sciences

**Full name of responsible person**

seyyed Ali Mozaffarpur

**Position**

Associated Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3219 4730

**Email**

seyyedali1357@gmail.com

Associated Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3279 4730

**Email**

seyyedali357@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

seyyed Ali mozaffarpur

**Position**

Associated Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3219 4730

**Email**

seyyedali1357@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

seyyed Ali Mozaffarpur

**Position****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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

all data will be accessible

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

people working in academic institutions

**Under which criteria data/document could be used**

systematic review and meta-analysis on data

**From where data/document is obtainable**

Submit a request via email seyzedali1357@gmail.com and after checking by the project manager

**What processes are involved for a request to access data/document**

Submit a request via email seyzedali1357@gmail.com and after checking by the project manager

**Comments**