

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the Efficacy of Cassia Fistula syrup on functional chronic constipation in chronic kidney disease (CKD) patients in comparison with the Lactulose (A Randomized Clinical Trial)

Protocol summary

Study aim

Main Objective: Determining the efficacy of Cassia Fistula syrup on functional chronic constipation in chronic kidney disease patients comparing to Lactulose according to ROME IV Specific objectives: 1-Determining number of defecation per week in consumption of Cassia Fistula comparing to lactulose 2-Amount of straining in....3-Amount of stool stiffness in....4-Amount of feeling of incomplete emptying per week....5-Amount of using manual maneuvers...6-Side effects of syrup based on visits and lab tests

Design

In this randomized clinical trial, 66 patients with chronic kidney disease having constipation, will be assigned randomly with single blindness into two parallel groups of drug and control, followed up for 2 weeks.

Settings and conduct

The population is patients with chronic kidney disease having constipation who are being treated in nephrology fields of Babol University of Medical Sciences. It will be performed as a single-blind (assessor blind) study with uniformity of drug packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Chronic kidney disease patients with constipation 2.Age between 18-80 years 3.Having at least two criteria of ROME IV Exclusion criteria: 1.Sensitivity to Cassia Fistula 2.Active infection in last month 3.Surgery on GI 4.Pregnancy 5.Organic constipation

Intervention groups

Patients with chronic kidney disease having constipation are divided into two groups. The medication group is given 30cc of Cassia Fistula syrup daily divided into 3 doses for 14 days and the control group is given 30cc of lactulose divided into 3 doses daily. Patients will be visited before the start of treatment, on the 7th and 14th day and follow-up will be done one week after the end of

treatment.

Main outcome variables

Frequency of defecation; straining in defecation; Frequency of hard stools; Feeling of incomplete emptying; Using manual maneuver; Stiff stools

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046009N6**

Registration date: **2022-06-02, 1401/03/12**

Registration timing: **prospective**

Last update: **2022-06-02, 1401/03/12**

Update count: **0**

Registration date

2022-06-02, 1401/03/12

Registrant information

Name

Seyyed Ali Mozaffarpur

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

dr.mozaffarpur@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-06, 1401/03/16

Expected recruitment end date

2022-08-07, 1401/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy of Cassia Fistula syrup on functional chronic constipation in chronic kidney disease (CKD) patients in comparison with the Lactulose (A Randomized Clinical Trial)

Public title

The Efficacy of Cassia Fistula syrup on functional chronic constipation in chronic kidney disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic kidney disease patients (CKD) with constipation
Age between 18 to 80 years Having at least two criteria of ROME IV

Exclusion criteria:

History of sensitivity to Cassia Fistula History of active infection in last month History of any surgery on GI system Pregnant women Organic constipation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Randomization is done using random permutation block methods. Random sequence generation is done online using the website www.sealedenvelope.com. The size of the blocks is 4. Drugs in two categories (intervention and standard treatment) are poured into identical containers by the pharmacist and sent to the study statistician. 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. Unlocking the codes will be done after the end of the study. In case of side effects, the drug code will be unlocked. Concealment: Drugs in groups A and B (without explanation of its content), reach the statistician and she performs the coding in blocks of four.

Blinding (investigator's opinion)

Single blinded

Blinding description

Lactulose and Cassia Fistula syrups will be provided in a single form, with the same label by a pharmacist in the laboratory of medicinal plants 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, shape and taste of the drugs are different, it is not possible to blind the patients in this regard. Therefore, the study will be done as a single blind (assessor blind) study with uniform packaging.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol University of Medical Sciences

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Babol University of Medical sciences, Sargord
Ghasemi avenue, Babol

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Mazandaran

Postal code

4718647745

Approval date

2022-05-29, 1401/03/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.075

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

chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

2**Description of health condition studied**

functional chronic constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of defecation

Timepoint

Number of defecation per week

Method of measurement

Data gathering questionnaire

Secondary outcomes

1

Description

Frequency of straining in defecation

Timepoint

Frequency of straining in defecation per week

Method of measurement

Data gathering questionnaire

2

Description

Feeling of incomplete emptying after defecation

Timepoint

Feeling of incomplete emptying after defecation per week

Method of measurement

Data gathering questionnaire

3

Description

Frequency of using manual maneuver

Timepoint

Number of applying manual maneuver for defecation per week

Method of measurement

Data gathering questionnaire

Intervention groups

1

Description

Intervention group: This group is given 30 cc of Cassia Fistula syrup (SANABEL DAROU Co.) daily divided into 3 doses for 14 days. Patients will be visited before the start of treatment, on the seventh day and the fourteenth day after the start of treatment and follow-up will be done one week after the end of treatment.

Category

Treatment - Drugs

2

Description

Control group: This group is given 30 cc of routine medicine, lactulose, (EXIR Co.) divided into 3 doses daily. Patients will be visited before the start of treatment, on

the seventh day and the fourteenth day after the start of treatment and follow-up will be done one week after the end of treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roohani Hospital

Full name of responsible person

Seyyed Ali Mozaffarpur

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Roohani Hospital, Babol University of Medical Sciences, Ganjafrooz Ave, Babol

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Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

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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

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyyed Ali Mozaffarpur

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

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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	accordance with the rules and regulations.
Study Protocol	When the data will become available and for how long
Yes - There is a plan to make this available	The access period will start 6 months after the results are published.
Statistical Analysis Plan	To whom data/document is available
Yes - There is a plan to make this available	Researchers working in academic and scientific institutions
Informed Consent Form	Under which criteria data/document could be used
Yes - There is a plan to make this available	Systematic review and meta-analysis of data
Clinical Study Report	From where data/document is obtainable
Yes - There is a plan to make this available	Submit a request via email to seyedali1357@gmail.com and after review by the project manager
Analytic Code	What processes are involved for a request to access data/document
Undecided - It is not yet known if there will be a plan to make this available	Submit a request via email to seyedali1357@gmail.com and after review by the project manager
Data Dictionary	Comments
Undecided - It is not yet known if there will be a plan to make this available	
Title and more details about the data/document	
Information will be accessible after publication in	