Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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)

Phone

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Email address

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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
Street address
Babol University of Medical sciences, Sargord Ghasemi avenue, Babol
City
Babol
Province
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
Street address
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2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Shahid Beheshti Hospital, , Babol University of Medical Sciences, Shahid Keshvari Square, Babol
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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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Seyyed Ali Mozaffarpur

Position
Associate Professor

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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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Associate Professor

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Email
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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

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

Information will be accessible after publication in accordance with the rules and regulations.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Systematic review and meta-analysis of data

From where data/document is obtainable

Submit a request via email to seyyedali1357@gmail.com and after review by the project manager

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

Submit a request via email to seyyedali1357@gmail.com and after review by the project manager

Comments