

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of Cassia fistula syrup on quality of life in patients undergoing hemodialysis with constipation

Protocol summary

Study aim

determination The effect of Cassia fistula syrup on quality of life in patients undergoing hemodialysis with constipation

Design

In this study, which was performed as a randomized placebo-controlled clinical trial in a three-way blind and phase 3 study on 106 patients, randomization was performed using the randomized permutation block method.

Settings and conduct

Patients undergoing hemodialysis, referred to hemodialysis centers of Shahrekord University of Medical Sciences and having a diagnosis of constipation are randomly assigned to two groups of drugs and placebo. A single shape, with the same label and the same taste and smell will be prepared by a pharmacist in the laboratory of the Clinical Trial Research Center of Shahed University. The only person who knows the nature of syrups is the pharmacist who makes the medicine. To hide the treatment process (Concealment), the drugs in two groups A and B (without explaining its content), reach a statistician and he performs the coding in blocks of four.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years and above - having at least two criteria of Rome-3 criteria Criteria for non-inclusion: - No gastrointestinal diseases, including irritable bowel syndrome, secondary constipation or neurological diseases (Parkinson, depression, etc.), non-neurological diseases (hypothyroidism, hypokalemia, etc.) - History of any surgery digestive system

Intervention groups

The drug group is given 10% Cassia fistula syrup in the amount of 10 ml twice a day for 30 days. The same amount of placebo syrup is given. If constipation does not improve, patients can increase the dose of the drug or placebo to 30 ml per day.

Main outcome variables

Quality of Life ; Constipation; Itching

General information

Reason for update

After conducting the pilot study and re-determining the size of the sample as well as the total number of patients eligible to enter the study, the number of samples was reduced to 70 people

Acronym

IRCT registration information

IRCT registration number: **IRCT20210202050229N1**

Registration date: **2021-08-02, 1400/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-18, 1401/06/27**

Update count: **1**

Registration date

2021-08-02, 1400/05/11

Registrant information

Name

Sadegh Shirvanifarsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3323 4227

Email address

sadegh.shirvani@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Cassia fistula syrup on quality of life in patients undergoing hemodialysis with constipation

Public title
The effect of Cassia fistula syrup on constipation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and above Dialysis adequacy index above 1/2 At least 3 months have passed since the start of hemodialysis Having at least two of the criteria of Rome-3
Exclusion criteria:
Sensitivity to plant compounds, especially Cassia fistula History of active infection in the last month Absence of gastrointestinal diseases including irritable bowel syndrome, secondary constipation or neurological diseases (Parkinson's, depression, etc.) Non-neurological diseases (hypothyroidism, hypokalemia, etc.) History of any gastrointestinal surgery

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done using random permutation blocks method. The size of the blocks is 4. Drugs in two categories (drug and placebo) are made 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 the codes will be done after the end of the study. In case of side effects, the drug code will be unlocked. Blinding is such that placebo syrup and medicine in a single form, with the same label and the same taste and smell will be prepared by a pharmacist in the laboratory of the Clinical Trial Research Center of Shahed University. The only person who knows the nature of syrups is the pharmacist who makes the medicine. To hide the treatment process (Concealment), the drugs in two groups A and B (without

explaining its content), reach a statistician and he performs the coding in blocks of four.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is such that placebo syrup and medicine in a single form, with the same label and the same taste and smell will be prepared by a pharmacist in the laboratory of the Clinical Trial Research Center of Shahed University. The only person who knows the nature of syrups is the pharmacist who makes the medicine.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahed University

Street address
Shahed university - Opposite Holy Shrine of Imam Khomeini- Khalij Fars Expressway - Tehran - Iran

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2021-05-31, 1400/03/10

Ethics committee reference number
IR.SHAHED.REC.1400.020

Health conditions studied

1

Description of health condition studied
quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of Life Score in the Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire

Timepoint
Measurement of quality of life before the intervention and 30 days after the start of Cassia fistula syrup

Method of measurement

Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire

2

Description

Constipation score in the Constipation Assessment Scale (CAS)

Timepoint

Measurement of Constipation before the intervention and 30 days after the start of Cassia fistula syrup

Method of measurement

Constipation Assessment Scale (CAS)

3

Description

Frequency and frequency of defecation

Timepoint

Measurement of the frequency of defecation on a daily basis the start of Cassia fistula syrup

Method of measurement

Make a note in the checklist

4

Description

Stool consistency in the Bristol stool scale

Timepoint

Measurement of the stool consistency after each bowel movement after starting Cassia fistula syrup

Method of measurement

Bristol stool scale

5

Description

Digestive problems

Timepoint

Measurement of the Digestive problems after each bowel movement after starting Cassia fistula syrup

Method of measurement

Make a note in the checklist

6

Description

Measurement of blood sodium

Timepoint

Measurement of blood sodium before intervention, two weeks after and four weeks after intervention

Method of measurement

blood test

7

Description

Measurement of blood potassium

Timepoint

Measurement of blood potassium level before the intervention, two weeks after and four weeks after the intervention

Method of measurement

blood test

8

Description

Measurement of blood hemoglobin

Timepoint

Measurement of blood hemoglobin level before the intervention and four weeks after the intervention

Method of measurement

blood test

9

Description

Measurement of blood hematocrit

Timepoint

Measurement of blood hematocrit before intervention and four weeks after intervention

Method of measurement

blood test

10

Description

Blood platelet count

Timepoint

Measurement of blood platelet count before the intervention and four weeks after the intervention

Method of measurement

blood test

11

Description

Measurement of blood urea nitrogen

Timepoint

Measurement of blood urea nitrogen before intervention and four weeks after intervention

Method of measurement

blood test

12

Description

Measurement of blood Creatinine

Timepoint

Measurement of blood Creatinine levels before the intervention and four weeks after the intervention

Method of measurement

blood test

13

Description

Measurement of blood calcium

Timepoint

Measurement of blood calcium levels before the intervention and four weeks after the intervention

Method of measurement

blood test

14

Description

Measurement of blood phosphorus

Timepoint

Measurement of blood phosphorus before the intervention and four weeks after the intervention

Method of measurement

blood test

15

Description

Measurement of blood alkaline phosphatase

Timepoint

Measurement of blood alkaline phosphatase levels before the intervention and four weeks after the intervention

Method of measurement

blood test

16

Description

Blood CRP measurement

Timepoint

Measurement of blood CRP before intervention and four weeks after intervention

Method of measurement

blood test

17

Description

Measurement of PTH in the blood

Timepoint

Measurement of blood PTH before intervention and four weeks after intervention

Method of measurement

blood test

Secondary outcomes

1

Description

Itching score in the Itchy Quality of Life (ItchyQoL) questionnaire

Timepoint

Measurement of pruritus before the intervention and 30 days after the start of Cassia fistula syrup

Method of measurement

Itchy Quality of Life (ItchyQoL) questionnaire

Intervention groups

1

Description

Intervention group: The drug group is given 10% Cassia fistula syrup (each 1 ml containing one tenth of a gram of dried pulp of Cassia fistula fruit) in the amount of 10 ml twice daily for 30 days.

Category

Treatment - Drugs

2

Description

Control group: Placebo syrup is a combination of sugar and honey that turns dark after preparation and heating and is prepared with a dosage defined by the Clinical Trial Research Center of Shahed University.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis centers affiliated to Shahrekord University of Medical Sciences

Full name of responsible person

Sadegh Shirvani Farsani

Street address

in front of the gas station-Ayatollah Khamenei Boulevard

City

Farsan

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8861693313

Phone

+98 38 3322 7333

Fax

+98 38 3322 5074

Email

sadegh.shirvani1370@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr Zahra Kiasalari

Street address

Shahed university - Opposite Holy Shrine of Imam Khomeini- Khalij Fars Expressway - Tehran - Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 3565

Email

info@shahed.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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
Shahed University
Full name of responsible person
sadegh shirvanifarsani
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
The end of Abuzar Ghaffari ave , farsan
City
farsan
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8861868383
Phone
+98 38 3323 4227
Email
sadegh.shirvani1370@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University
Full name of responsible person
Mohammad Reza Heidari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tehran, Persian Gulf Highway (Tehran - Qom), facing

the holy shrine Imam Khomeini, Shahed University
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 2146
Email
mheidari@shahed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahed University
Full name of responsible person
sadegh shirvanifarsani
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
The end of Abuzar Ghaffari Ave , farsan
City
Farsan
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8861868383
Phone
+98 38 3323 4227
Email
sadegh.shirvani1370@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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