

# 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**

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##### **Phone**

+98 38 3322 7333

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##### **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

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##### **Province**

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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  
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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  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
sadegh shirvanifarsani  
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Masters student  
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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

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