

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Cassia Fistula syrup in geriatrics consipation 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)

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Email address

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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 consipation 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

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

Babol University of Medical Sciences

Full name of responsible person

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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
Associated Professor
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Person responsible for updating data

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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

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 seyyedali1357@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 seyyedali1357@gmail.com and after checking by the project manager

Comments