

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effectiveness of a topical preparation of Cassia fistula L. on navel for the treatment of functional constipation

Protocol summary

Study aim

The effectiveness of a topical product of Cassia Fistula L. on navel for the treatment of functional constipation.

Design

150 patients aged 18 to 50 years old with eligible functional constipation who were referred to the clinics of the Faculty of Traditional Medicine of Tehran University were divided into two groups, so that the two groups were matched in terms of age and sex, each patient had a code

Settings and conduct

The study is done at the traditional medicine clinics of Tehran University. A group involve 75 people, receive drug A and another group receive drug B for 2 weeks. After a washout period, the groups use another drug (A or B). The questionnaire was filled in the first and at the end of the second week and at the end of the last 2 weeks. The physician, the provider of the drug to the patient and statistics consultant are not informed about the drug or placebo status of the product. The drug and placebo are named in two categories A and B.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 and 50 and confirmation of functional constipation diagnosis based on the Rome III criteria. Exclusion Criteria: Pregnancy, breastfeeding, history of abdominal or gastrointestinal surgery, gastrointestinal bleeding, psychosis, recent surgery, serious heart or liver or endocrine disease (Diabet mellitus , thyroid dysfunction), cancer and anemia.

Intervention groups

Drug group: receive topical production of Cassia Fistula
Placebo group: receive topical production of placebo

Main outcome variables

Determine the effect of topical drug on the navel on: 1. Frequency of bowel movements per week 2. Stool consistency 3. Straining during evacuation 4. Sensation of incomplete defecation 5. Sensation of anorectal blockage 6. Manual maneuver to Facilitate defecation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170929036482N2**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **retrospective**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

mohsen keshavarz

Name of organization / entity

tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 3656

Email address

keshavarzm@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

tehran university

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

2016-04-02, 1395/01/14

Actual recruitment end date

2017-06-10, 1396/03/20

Trial completion date

2017-06-20, 1396/03/30

Scientific title

The effectiveness of a topical preparation of Cassia fistula L. on navel for the treatment of functional constipation

Public title

The effectiveness of a topical form of Cassia fistula L. on Constipation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 50 years Confirmation of functional constipation diagnosis based on Rome III criteria

Exclusion criteria:

Pregnancy, , , , , , Lactating women History of abdominal surgery Gastrointestinal bleeding Psychosis Recent surgery Serious Heart or Liver diseases or Endocrine disorders (Diabetes, Thyroid dysfunction) Cancer Anemia

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **150**

Actual sample size reached: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two groups by Permuted Block randomization. The number of blocks was 2, 4, and 6. Then, with the random numbers generated by the computer, the arrangement of the blocks was determined, and the blocks were sorted in the order in which the two drugs were placed. Based on the arrangement, the two groups of drugs were each written in one sheet and placed in the same envelope with a three-digit code on it. After identifying the conditions of entry into the study, the physician referred the patient to the person who provided the envelopes, and the person submitted the envelope to the patient without knowing the contents of the envelope by inserting a three digit number on the patient's envelope. Then he opened the envelope pharmacy technician and, according to the inscription in the envelope marked A and B, provided the patient with the drugs named by the same name and no other information on the drug label. In this study, the doctor was unaware of the patient's position in the drug groups, the secretary and the pharmacist and the patient himself were unaware. At the end of the study, the three-digit code, patient group and results of the three stages (before the study, the second

week, the fourth week) were delivered to the statistical adviser and the results were obtained.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo are delivered in 2 separate packages A and B, to the person in charge of delivery of the medication, and they do not have any information on the content. The physician and researcher who is the same person does not know what medicine they received. Statistics analyze and compare the two groups on the basis of the data without knowing the drug type of each group. Just the fourth person who has delivered the medication to the person in charge of delivery of the medication knows drug and placebo group.

Placebo

Used

Assignment

Crossover

Other design features

no

Secondary Ids

empty

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

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab square

City

Tehran

Province

Tehran

Postal code

۶۶۱۹-۱۴۱۵۵

Approval date

2016-04-02, 1395/01/14

Ethics committee reference number

8921309006

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

Functional Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of defecation per week

Timepoint

Before the study, end of week 2, end of week 4

Method of measurement

A questionnaire based on Rome III criteria

2

Description

Frequency of hard stool

Timepoint

Before the study, end of week 2, end of week 4

Method of measurement

A questionnaire based on Rome III criteria

3

Description

Frequency of straining during defecation

Timepoint

Before the study, end of week 2, end of week 4

Method of measurement

A questionnaire based on Rome III criteria

4

Description

Frequency of sensation of incomplete evacuation

Timepoint

Before the study, end of week 2, end of week 4

Method of measurement

A questionnaire based on Rome III criteria

5

Description

Frequency of sensation of anorectal blockage

Timepoint

Before the study, end of week 2, end of week 4

Method of measurement

A questionnaire based on Rome III criteria

6

Description

Frequency of manual maneuvers to facilitate defecation

Timepoint

Before the study, end of week 2, end of week 4

Method of measurement

A questionnaire based on Rome III criteria

Secondary outcomes

1

Description

Skin complication at the site of topical use

Timepoint

Before study, end of week 2, end of week 4

Method of measurement

A questionnaire

2

Description

Any possible complications

Timepoint

Before study, end of week 2, end of week 4

Method of measurement

A questionnaire

Intervention groups

1

Description

Patients were divided into two groups A and B. During the first two weeks, group A received Cassia fistula or placebo. Subsequently in one weeks, they did not receive any medication (washout time) up to a week. Then, for 2 weeks, group A received another drug (cassia fistula or placebo). The patients apply the drug and placebo to the navel, six times at day and each time six gram.

Category

Treatment - Drugs

2

Description

Patients were divided into two groups A and B. During the first two weeks, group A received Cassia fistula or placebo. Subsequently in one weeks, they did not receive any medication (washout time) up to a week. Then, for 2 weeks, group A received another drug (cassia fistula or placebo). The patients apply the drug and placebo to the navel, six times at day and each time six gram.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Medicine clinic of Tehran University of Medical Sciences

Full name of responsible person

Mohsen Keshavarz

Street address

Khark traditional medicine clinic, Khark street, Valiasr crossroad

City

Tehran

Province

Tehran

Postal code

1133855113

Phone

+98 21 6675 4153

Fax

+98 21 6675 4153

Email
herbal_med777@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Traditional Medicine school of Tehran University

Full name of responsible person
Fatemeh Taheri

Street address
No. 67, Giti avenue, Wafamanesh street, Heravi square

City
Tehran

Province
Tehran

Postal code
1668753961

Phone
+98 21 2298 8550

Email
STPM@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Traditional Medicine school of Tehran 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
Tehran University

Full name of responsible person
Mohsen Keshavarz

Position
Physician and resident of Traditional Medicine -
Schedule Executive

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Ahmadiye Clinic, Traditional Medicine school, Felestin Square

City

Tehran
Province
Tehran
Postal code
1416663361
Phone
+98 21 8899 3656

Fax
Email
herbal_med777@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Traditional Medicine school of Tehran University

Full name of responsible person
Mohsen Keshavarz

Position
Professional Doctor

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Traditional Medicine school of Tehran University

City
Tehran

Province
Tehran

Postal code
1668753961

Phone
+98 21 8899 3656

Fax
Email
herbal_med777@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Traditional Medicine school of Tehran University

Full name of responsible person
Mohsen Keshavarz

Position
Physician and student of Traditional Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Ahmadiyah clinic, Traditional Medicine school,
Felestin Square

City
Tehran

Province
Tehran

Postal code

1416663361

Phone

+98 21 8899 3656

Fax

Email

herbal_med777@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information and biographies and examinations to enter the study - Questionnaires at 3 times mentioned - Statistical methods

When the data will become available and for how long

Since the beginning of 2018 March

To whom data/document is available

All Researchers in all disciplines

Under which criteria data/document could be used

There is no condition

From where data/document is obtainable

Email: herbal_med777@yahoo.com

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

Documents will be submitted to the applicant for a maximum of 1 month.

Comments