

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Effect of Ayarij-e-Faiqra on functional constipation in adults referring to Clinic

Protocol summary

Study aim

In this research, we investigate the effect of Ayarij-e-Faiqra on functional constipation

Design

The study was a double-blind randomized clinical trial. patients randomized into two groups, according to a randomization code generated by computer software with 40 in each group. In the situation of intolerant of constipation, the patient could use a laxative, which was a tablet (C-lax).

Settings and conduct

The present study performed the effect of AF on functional constipation symptoms in adults referring to the traditional medicine clinic of Shahid Beheshti University of Medical Sciences. Before the start of the study, all patients visited and 79 patients after proving the existence of functional constipation with ROME III criteria, volunteering, and checking the Inclusion and Exclusion criteria, Were divided Into two randomized, double-blind, drug and placebo groups. The designed questionnaires and visual analog scale were measured by the researcher at the end of the first, second, third month, and three months after the end of the intervention.

Participants/Inclusion and exclusion criteria

aged 18-50 years, the ability to participate in the whole study, the absence of significant behavioral disorders, speech in understandable language, completion of the consent form and have at least six months of history of constipation according to Rome III criteria. Exclusion: Patients who do not meet any of the entry criteria. Lack of desire to participate in the study, lack of cooperation and having a case of disorders that affect functional constipation (intestinal obstructive diseases, pregnancy, breastfeeding, etc.)

Intervention groups

The Ayarij-e-Faiqra group-The placebo group

Main outcome variables

Straining, hard stools, Sensation of incomplete

evacuation, the sensation of anorectal obstruction, Manual maneuvers, Fewer than three defecations per week, Loose stools, satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046677N1**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **retrospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

rasool choopani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

rchoopani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2014-04-21, 1393/02/01

Actual recruitment end date

2016-07-22, 1395/05/01

Trial completion date
2016-07-22, 1395/05/01

Scientific title
Effect of Ayarij-e-Faiqra on functional constipation in adults referring to Clinic

Public title
Effect of Ayarij-e-Faiqra on functional constipation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The ability to participate in the whole study
Absence of significant behavioral disorders
Speech in understandable language
Completion of the consent form and having at least six months of history of constipation according to Rome III criteria.
Exclusion criteria:
Sensitivity to herbal medicines
Diagnosis of obstructive constipation by a gastroenterologist based on history or colon transit
Consumption drugs that cause constipation in the recent month (anticholinergic drugs, tricyclic antidepressants, calcium channel blockers, anti-Parkinson's drugs, sympathomimetics, antipsychotics, diuretics, iron supplements, anti-inflammatory drugs, hormonal drugs)
Abuse narcotics, stimulants, cannabis, alcohol and pseudo pirates
Illnesses affecting constipation
Warning signs (rectal bleeding, weight loss or anemia)
Unpredictable complications were leading to intolerance to the drug or placebo such as idiosyncratic disease
Secondary constipation to diseases, and medications
Gastrointestinal complications that impede the continuation of the study
Unwilling to continue the study and lack of cooperation.

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: **80**
Actual sample size reached: **79**

Randomization (investigator's opinion)
Randomized

Randomization description
patients eligible for randomization to one of two drug or placebo groups, according to a randomization table generated by computer excel software. The prescribing physician, assistant, and patient will not be aware of any capsules content, and the capsules code will be written to the file (double-blind). Randomization Unit: Individual
Randomization Tool: randomization table

Blinding (investigator's opinion)
Double blinded

Blinding description
The capsules code will be written to the file. The Prescribing physician, assistant, and patient will not be aware of any capsules content. (Double-blind).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
the Medical Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
tehran
Province
Tehran
Postal code
1983963113

Approval date
2014-03-11, 1392/12/20

Ethics committee reference number
IR.SBMU.REC.1392.766

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
Straining during at least 25% of defecations

Timepoint
The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement
A questionnaire filled out by the researcher using the interview method

2

Description

lumpy or hard stools in at least 25% of defecations

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

A questionnaire filled out by the researcher using the interview method

3

Description

The sensation of incomplete evacuation for at least 25% of defecations

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

A questionnaire filled out by the researcher using the interview method

4

Description

Sensation of anorectal obstruction/blockage for at least 25% of defecations

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

A questionnaire filled out by the researcher using the interview method

5

Description

Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

A questionnaire filled out by the researcher using the interview method

6

Description

Fewer than three defecations per week

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

A questionnaire filled out by the researcher using the interview method

7

Description

loose stools are rarely present without the use of laxatives

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

A questionnaire filled out by the researcher using the interview method

8

Description

Patient satisfaction

Timepoint

The end of 1, 2, 3 months, and three months after the end of the intervention

Method of measurement

Using the visual analogue scale questionnaire, ten scores were filled in by the researcher using the interview method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ayarij-e-Faiqra. AF was prepared according to the "Qarabadin Kabir" textbook. prepared under the supervision of the professors of pharmacy of the Faculty of Traditional Medicine by identifying single drugs, quality control of medicinal plants, processing, and preparation of formulation and microbial control based on the latest available standards. It was a combination of Cinnamomum zeylanicum bark, Pistacia lentiscus oleo gum resin, Cinnamomum cassia bark, Asarum europaeum rhizome, Commiphora opobalsamum fruit and wood, and Nardostachys jatamansi rhizome, Crocus sativus stigma and Aloe vera juice (1:1:1:1:1:1:0.14:7.14). All the components were powdered, sieved and mixed, then packed in 500 mg hard gelatin capsules. The daily dose of the drug was 1-2 capsules, half an hour before bedtime with warm water and the duration of intervention was three months. At first, each patient consumed one capsule every night, and if he/she had not enough bowel movements, the dose increased to two capsules/day. In the situation of intolerant of constipation, the patient could use a laxative, which was a tablet (C-lax) containing senna leaf.

Category

Treatment - Drugs

2

Description

Control group: placebo. The placebo was prepared from corn starch in the same color and size capsules. The daily dose of the placebo was 1-2 capsules, half an hour before bedtime with warm water and the duration of intervention was three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Medicine Clinic of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Rasool Choopani

Street address

No.8, Valiasr Ave., shams Ali

City

tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

rchoopani@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Esmaeili

Street address

No.8, Valiasr Ave., shams Ali

City

tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

sesmaeili@sbmu.ac.ir

Grant name

Research Assistant of Shahid Beheshti University of
Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.8, Valiasr Ave., Shams Ali

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

rchoopani@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

Street address

No.8, Valiasr Ave., Shams Ali

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax

Email

rchoopani@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

Street address

no 8 .Valiasr Tehran Province, Tehran, District 6,
Shams

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax**Email**

rchoopani@sbmu.ac.ir

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