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)

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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

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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 (1:1:1:1:1:1:1:0.14:7.14). 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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

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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