

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Assessment of the impacts of Traditional Persian Medicine measures on the functional chronic constipation compared to those of Allopathic Medicine

Protocol summary

Summary

Title: Assessment of the impacts of Traditional Persian Medicine measures on the functional chronic constipation compared to those of Allopathic Medicine. Aims: To compare Lactulose+Traditional Persian Medicine with Lactulose (only) on the functional chronic constipation and assess clinical efficacy and side effects. Design: The study is blocked randomized, double blind study. Setting and conduct: After obtaining informed consent from the patients that refer to Motahari polyclinic, the patients divide into two parallel therapeutic groups through a block randomization. The sample size was determined based on similar studies. 20 patients, aged 18-80 years who meet the Rome-3 criteria are enrolled in this pilot study with a block randomization (10 in each group). Major Inclusion and Exclusion criteria: Inclusion criteria: At least two criteria of ROM-3 Criteria should be observed; Chronic constipation should be confirmed via complete physical examination if needed. Exclusion criteria: Suspicious to organic disorders. Intervention: Intervention group, will receive Lactulose and Persian traditional medicine as change of lifestyle with face to face interview and weekly follow up with standard questionnaire for 1 month and control group, will receive Lactulose only. Main outcome measures (variables): Stool frequency, Hard stool, Painful defecation, Sensation of incomplete evacuation, Sensation of anorectal obstruction, Manual maneuvers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070915587N6**

Registration date: **2014-08-23, 1393/06/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-23, 1393/06/01

Registrant information

Name

Nasrin Naseri

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4263

Email address

grc@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the impacts of Traditional Persian Medicine measures on the functional chronic constipation compared to those of Allopathic Medicine

Public title

Impacts of Traditional Persian Medicine on the

constipation management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least two criteria of ROM-3 Criteria should be observed; Chronic constipation should be confirmed via complete physical examination if needed. Exclusion criteria: Suspicious to organic disorders; Obstructive disorders; Metabolic etiologies; Neurological problems.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz, Fars, Iran

City

Shiraz

Postal code

Approval date

2014-05-14, 1393/02/24

Ethics committee reference number

7210-13-01-93

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of bowel movements per week

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

2

Description

Frequency of hard or lumpy stool in bowel movements per week

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

3

Description

Frequency of strain during bowel movements per week

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

4

Description

Frequency of incomplete emptying after bowel movements per week

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

5

Description

Frequency of sensation of anorectal obstruction/blockage per week

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

6

Description

Frequency of manually maneuvers usage per week

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

Secondary outcomes

1

Description

symptoms of chronic constipation based on the international diagnostic criteria of ROM-3 chronic constipation

Timepoint

Before intervention and at the end of every week, during intervention period (for one month)

Method of measurement

International questionnaire for diagnostic criteria of chronic constipation-ROM3

Intervention groups

1

Description

Intervention group: Lactulose and measures recommended in Persian Traditional Medicine resources changing in lifestyle with face to face interview and weekly follow up with standard questionnaire for 1 month.

Category

Lifestyle

2

Description

Control group: Lactulose [a disaccharide (double-sugar) formed from one molecule each of the simple sugars (monosaccharides) fructose and galactose, syrup, 10g/15ml, 10cc, 3times/day, for 1 month, Sobhan Co.] per se.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari polyclinic

Full name of responsible person

Seyed Morteza Emami Alorizi

Street address

Namazi Hospital, Namazi square, Zand street, Shiraz, Fars, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz, Fars, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Motahari polyclinic

Full name of responsible person

Seyed Morteza Emami Alorizi

Position

PhD student in Persian Traditional Medicine

Other areas of specialty/work

Street address

Namazi Hospital, Namazi square, Zand street, Shiraz, Fars, Iran

City

Shiraz

Postal code

Phone

+98 71 1647 4263

Fax

Email

smemami@sums.ac.ir; morteza.emami@gmail.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Gastroenterohepatology Research Center

Full name of responsible person

Mohamad Reza Fatahi

Position

Associate professor

Other areas of specialty/work

Street address

Namazi Hospital, Namazi square, Zand street, Shiraz,
Fars, Iran

City

Shiraz

Postal code

Phone

+98 71 1647 4263

Fax

Email

fattahi@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty