

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Assessment of the impacts of Traditional Persian Medicine devises on the functional chronic constipation compared to those of Classic Medicine

Protocol summary

Summary

Chronic constipation is a common complaint in practical evaluations. Prevalence of constipation is up to 12% of people worldwide. People in the United States and Asia-Pacific suffer twice as much as their European counterparts. The epidemiology surveys which explored duration and frequency of constipation in Iran show high frequency of constipation in Iran. We have not seen the exact term of constipation in Traditional Persian Medicine manuscripts (TPM) which may be due to different methodology of TPM in comparison to the Classic Medicine. In TPM, basis of diagnosis and treatment are the patient temperaments and affected organs. Based on the remaining documents and lack of the related treatments in current medicine for long term therapy as well as high frequency of constipation in world and Iran and poor life style, we will try to compile a practical, preventive, safe and effective method for the management of the chronic constipation. Endpoints or results of this research can produce considerable, effective and more practical approaches to control the functional chronic constipation. Following the study of many main traditional Persian medical manuscripts, it was outlined that due to focuses of TPM on prophylactic health methods, six schemes of health are spoken as the first line in prophylactic and curative approaches in diseases. Compared to other advises of TPM, application of these schemes can be considered as an elective, major and effective method for the chronic constipation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031016925N1**

Registration date: **2014-06-22, 1393/04/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-22, 1393/04/01

Registrant information

Name

Seyed Morteza Emami Alorizi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

smemami@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the impacts of Traditional Persian Medicine devises on the functional chronic constipation compared to those of Classic 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

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

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

Mashhad University of Medical Sciences

Street address

Doctora cross, Daneshgah Ave., Mashhad

City

Mashhad

Postal code

Approval date

2014-05-12, 1393/02/22

Ethics committee reference number

922405

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

weekly

Method of measurement

Questionnaire based on the international diagnostic criteria of chronic constipation-ROM3

2

Description

Frequency of hard or lumpy stool in bowel movements per week

Timepoint

weekly

Method of measurement

Questionnaire based on the international diagnostic criteria of chronic constipation-ROM3

3

Description

Frequency of strain during bowel movements per week

Timepoint

weekly

Method of measurement

Questionnaire based on the international diagnostic criteria of chronic constipation-ROM3

4

Description

Frequency of incomplete emptying during bowel movements per week

Timepoint

weekly

Method of measurement

Questionnaire based on the international diagnostic criteria of chronic constipation-ROM3

5

Description

Frequency of sensation that the stool could not be passed or obstruction per week

Timepoint

weekly

Method of measurement

Questionnaire based on the international diagnostic criteria of chronic constipation-ROM3

6

Description

Frequency of manually maneuvers usage per week

Timepoint

weekly

Method of measurement

Questionnaire based on the international diagnostic

criteria of chronic constipation-ROM3

Secondary outcomes

1

Description

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

Timepoint

weekly

Method of measurement

Questionnaire based on the international diagnostic criteria of chronic constipation-ROM3

Intervention groups

1

Description

One Group uses TPM prophylactic health method that this method is as a type of lifestyle change education with face to face interview and weekly follow up with standard questionnaire, for 3 months.

Category

Lifestyle

2

Description

One group uses lactulose only. lactulose (syrup,10g/15ml,10cc,3times/day,for 3months)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahary martyr clinic

Full name of responsible person

Seyed Morteza Emami Alorizi

Street address

Namazi square, Zand blv., Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Ahmad Saghebi

Street address

Doctora cross, daneshgah Ave., Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

School of Traditional Medicine of Mashhad

Full name of responsible person

Seyed Morteza Emami Alorizi

Position

Postgraduate student of Traditional Medicine, Persian Traditional Medicine Resident

Other areas of specialty/work

Street address

After Sina Hospital, Razi Ave., Mashhad

City

Mashhad

Postal code

Phone

+98 51 1855 2188

Fax

Email

smemami@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Traditional Medicine of Mashhad

Full name of responsible person

Seyed Ahmad Saghebi

Position

Head of Mashhad Traditional Medicine Department, Associated Professor

Other areas of specialty/work

Street address

After Sina Hospital, Eastern Razi Ave., Mashhad

City

Mashhad

Postal code

Phone

+98 51 1855 2188

Fax

Email

saghebiA@mums.ac.ir

Web page address

Phone

+98 51 1855 2188

Fax

Email

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Morteza Emami Alorizi

Position

Post graduate student of Traditional Persian
Medicine, Traditional Persian Medicine Resident

Other areas of specialty/work

Street address

After Sina Hospital, Eastern Razi Ave., Mashhad

City

Mashhad

Postal code

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