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
Motivehary 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
Mashhad University of Medical Sciences

Full name of responsible person
Seyed Ahmad Saghebi

Street address
Doctora cross, daneshgah Ave., Mashhad

City
Mashhad

Grant name
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

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
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