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**
Double blinded

**Blinding (investigator's opinion)**
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
1393/02/22

Approval date
2014-05-12

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
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
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
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Phone
+98 51 1855 2188
Fax
empty
Email
smemami@sums.ac.ir
Web page address
empty

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
empty
Phone
empty
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

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