

# 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

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**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*