Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

determination of the efficacy of ''Malva sylvestris"on adult functional constipation in Traditional Iranian Medicine.

Protocol summary

Summary

This study evaluates efficacy of'" Malva sylvestris" in patients with functional constipation from Iran. Inclusion criteria:Men and women aged 18–65 years with a history of chronic constipation are eligible for the study. Functional constipation was defined according to the criteria of the Rome III as having at least two or more of the following, during 25% of defecation times: 1, straining; 2, lumpy or hard stools; 3, sensation of incomplete evacuation; 4, manual manoeuvres to facilitate defecation; and 5, fewer than three defecations per week. These criteria should have been fulfilled for the 3 previous months with symptom onset at least 6 months prior to diagnosis. Exclusion criteria includes patients with any of the following conditions: Patients with alarming symptoms (fever, recent weight loss , and anaemia), drug-induced constipation, those with coexisting secondary causes of chronic constipation, including endocrine, metabolic, or neurological disorders, patients with a history of gastrointestinal surgery(exception of appandectomy and cholecystectomy),those with a diagnosis of constipation dominant IBS. This study is Double-blind, randomized, placebo-controlled clinical trial. 110 patients are assigned to two treatment groups , malva sylvestris or placebo groups.The malva sylvestris or placebo is given as syrup with the same shape and colour, twice daily after breakfast and after lunch for 4 weeks. The primary outcome measures are , defaecation rate, stool consistency according to the Bristol Stool Form scale, difficulty on defaecation, sensation of incomplete evacuation, or a need for digital manipulation to facilitate evacuation, are evaluated at baseline, 2 and 4 weeks later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031617032N1**
Registration date: **2014-07-12, 1393/04/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-12, 1393/04/21

Registrant information

Name
Mahin Elsagh
Name of organization / entity
Faculty of Traditional Medicines, Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 3395 0154
Email address
elsaghm@yahoo.com

Recruitment status

Recruitment complete

Funding source

Faculty of Traditional Medicines,Tehran University of Medical Sciences.

Expected recruitment start date

2013-12-11, 1392/09/20

Expected recruitment end date

2014-12-11, 1393/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

determination of the efficacy of ''Malva sylvestris"on

adult functional constipation in Traditional Iranian Medicine.

Public title
Efficacy of ''Malva sylvestris"on functional constipation .
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Men and women aged 18–65 as having at least two or more of the following, during 25% of defecation times: very hard and/or hard stools; sensation of incomplete evacuation; straining at defecation; a need for digital manipulation to facilitate evacuation.These criteria should have been fulfilled for the 3 previous months with symptom onset at least 6 months prior to diagnosis. Exclusion criteria:Men and women <18 years;Men and women>65 years;patients with mentioned criteria & drug-induced constipation, patients suffering from secondary causes of chronic constipation, including endocrine, metabolic, or neurological disorders; patients with a history of gastrointestinal surgery(exception of appandectomy and cholecystectomy); those with a diagnosis of constipation dominant IBS; Patients with alarming symptoms (fever, recent weight loss , and anaemia)& constipation.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Institue for Islamic & Complementary Medicine
Street address
No.9, Pirnia alley, Lalehzar St., Jomhury Ave., Tehran, IRAN
City
Tehran
Postal code
Approval date
2013-03-03, 1391/12/13
Ethics committee reference number
1106/پ26/م/ط

Health conditions studied

1

Description of health condition studied
constipation
ICD-10 code
K59.0
ICD-10 code description
constipation

Primary outcomes

1

Description
defecation rate per week on average
Timepoint
before interventing &2,4 weeks aftertreatment
Method of measurement
ROME III questionnaire

2

Description
hard stools
Timepoint
before interventing & 2,4 weeks aftertreatment
Method of measurement
ROME III questionnaire& Bristol stool form scale

3

Description
need for digital manipulation to facilitate evacuation
Timepoint
before interventing & 2,4 weeks aftertreatment
Method of measurement
ROME III questionnaire

4

Description
sensation of blockage
Timepoint
before interventing & 2,4 weeks aftertreatment
Method of measurement
ROME III questionnaire

5

Description
straining of defecation
Timepoint

before interventing & 2,4 weeks aftertreatment

Method of measurement

ROME III questionnaire

Secondary outcomes

1

Description

rarely dyspepcia

Timepoint

every time patient reports.

Method of measurement

patient report.

Intervention groups

1

Description

In malva sylvestris group, syrup is given 10cc twice daily,2 hours after breakfast and lunch for 4 weeks.

Category

Treatment - Drugs

2

Description

In placebo group, DW50% syrup approves 10 cc twice daily,2hours after breakfast and lunch for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Integrative Functional Gastroenterology Research Center

Full name of responsible person

Mahin Elsagh

Street address

Shariati St,Integrative Functional Gastroenterology Research Center

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Traditional Medicines,Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Shams Ardekani

Street address

on the corner of Behesht St,Vahdat Islami St, Faculty of Traditional Medicines,Tehran,Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Traditional Medicines,Tehran 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

Faculty of Traditional Medicines ,Iran University of Medical Science

Full name of responsible person

Mahin Elsagh

Position

phd student

Other areas of specialty/work

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave.,Faculty of Traditional Medicines, Iran University of Medical Science

City

Tehran

Postal code

Phone

+98 21 3395 0154

Fax

+98 21 3311 1619

Email

Elsaghm@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahin Elsagh

Position

phd student

Other areas of specialty/work

Street address

No.9, Pirnia alley, Lalehzar St., Jomhury Ave, Faculty

of Traditional Medicines,Iran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 3395 0154

Fax

Email

elsaghm@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Traditional Medicines,Iran University of Medical Sciences

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Position

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No.9, Pirnia alley, Lalehzar St., Jomhury Ave, Faculty of Traditional Medicines,Iran University of Medical Sciences

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Fax

+98 21 3311 1619

Email

elsaghm@yahoo.com

Web page address

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