

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

A Survey on Effectiveness of *Descureania Sophia L.* and *Pronus Domestica L.* for Prevention of Constipation in Haj Pilgrims in 2010: A Clinical Trial

Protocol summary

Summary

This survey has been established to evaluate the effectiveness of prune and flixweed in prevention of constipation in 2010 hajj pilgrims. 145 persons in each group (case and control) will be enrolled and a form containing demographic data, history of drug use, history of previous disease and so on would be filled out by physician and those who have history of any systemic disease or drug consumption would be ruled out. In case group, 10 grams flixweed in 250 cc warm water and 50 grams prune would be distributed every morning 30 minutes before breakfast. We will continue trial 3 weeks and then evaluate patients' constipation base on ROME III criteria. A new form will be filled out in the end of trial based on different constipation parameters (pain on defecation, bleeding, feeling of incomplete defecation, frequency of bowel movement) as primary outcome and other gastrointestinal symptoms (distention, bloating, dyspepsia, abdominal pain and bowel sounds) as secondary outcome by visual analog score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009013074N2**

Registration date: **2011-04-17, 1390/01/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-17, 1390/01/28

Registrant information

Name

Mehdi Pasalar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 7589

Email address

pasalar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Survey on Effectiveness of *Descureania Sophia L.* and *Pronus Domestica L.* for Prevention of Constipation in Haj Pilgrims in 2010: A Clinical Trial

Public title

A Survey on Effectiveness of Flex weed seeds and Prune for Prevention of Constipation in Haj Pilgrims in 2010: A Clinical Trial

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Registration in haj caravan under study. Exclusion criteria: a. Consumption of constipation forming drugs which couldn't disconnect them; b. Any gastrointestinal diseases like irritable bowel syndrome, Neurological diseases like Parkinson or Systemic

diseases like diabetes mellitus ; c.Any gastrointestinal system surgery; d.Laxative drugs consumption during trial.

Age

From **20 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Avenue, Central Buildig

City

Shiraz

Postal code

Approval date

2010-10-27, 1389/08/05

Ethics committee reference number

EC2781

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Constipation evaluation

Timepoint

Start and End of Trial

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Fullness, Distention, Dyspepsia, Abdominal Discomfort

Timepoint

Start and End of Trial

Method of measurement

Questionnaire

Intervention groups

1

Description

In case group, 10 grams flaxseeds in 250 cc water and 50 grams prune would be distributed every morning 30 minutes before breakfast. We will continue trial 3 weeks orally.

Category

Prevention

2

Description

There is no intervention in control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal Research Center

Full name of responsible person

Kamran Bagheri Lankarani

Street address

Shiraz

City

Mecca - Medina

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ,Shiraz University of Medical Sciences

Full name of responsible person

Dr.Hatam
Street address
Shiraz, Zand Avenue
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research ,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
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Person responsible for updating data

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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