

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

comparative survey of the effect of Plantagomajor and colofac on clinical sign of irritable bowel syndrome

Protocol summary

Summary

This study is a randomized controlled trial study that will be done on 50 women and man from the 23 July 2014 to 23 Octobr 2014 at the Gastroenterology Clinic in Rasoolakram Hospital in Tehran. The patients had clinical criteria (criteria Room II) stipulated in internal medicine and gastroenterology authoritative book on IBs .Intervention Group are consisted of 25 cases that intake one of the capsule that has 4.5 g of Plantago in two hours before lunch and two hours before dinner for 3 month. Control group are consisted of 25 cases that intake 200 mg of colofac capsule twice a day for 3 month. These groups will be observed every week in first month and every 2 weeks in second month and the end of third month. Study variables are: diarrhea, constipation, abdominal pain Data using SPSS-17 software and descriptive and inferential statistical tests (chi-square, T test, ANOVA and paired comparisons) will be analyzed. In this study, $P < 0.05$ was considered as statistically significant.

General information

Acronym

Plantago major and Colofac

IRCT registration information

IRCT registration number: **IRCT2014070118313N1**

Registration date: **2014-07-21, 1393/04/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-21, 1393/04/30

Registrant information

Name

Mostafa Salehi Najaf Abadi

Name of organization / entity

Traditional Medicine Faculty, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Traditional Medicine Faculty, Tehran University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative survey of the effect of Plantagomajor and colofac on clinical sign of irritable bowel syndrome

Public title

comparative survey of the effect of Plantagomajor and colofac on clinical sign of irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: patient with recognized IBS with Rome III criteria, age 15-45 years old, Exclusion:Refusal or failure to cooperate in treatment, cirrhosis, Sensitivity to plantago, heart failure, Chronic renal failure,Bowel Cancer, pregnancy,psychosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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**

Ethics Committee, Faculty of Traditional Medicine,
Tehran University of Medical Sciences

Street address

Keshavarz Blv Ghods St Tehran

City

Tehran

Postal code

1417653761

Approval date

2013-11-11, 1392/08/20

Ethics committee reference number

1773/130/92/3

Health conditions studied**1****Description of health condition studied**

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes**1****Description**

abdominal pain

Timepoint

Before the treatment and every week for tree month

Method of measurement

visual scale of pain

2**Description**

frequency of bowel habit

Timepoint

Before the treatment and every week for tree month

Method of measurement

questionnaire

Secondary outcomes**1****Description**

distention

Timepoint

befor intervention and every week for tree month

Method of measurement

questionnaire

Intervention groups**1****Description**

This study will be done on 25 patient from the 23 July 2014 to 23 October 2014 at the Gastroenterology Clinic in Rasoolakram Hospital in Tehran. Intervention Group are consisted of 25 cases that intake one of the capsule that has 4.5 g of Plantago in two hours before lunch and two hours before dinner for 3 month

Category

Treatment - Drugs

2**Description**

This study will be done on 25 patient from the 23 July 2014 to 23 October 2014 at the Gastroenterology Clinic in Rasoolakram Hospital in Tehran. Control group are consisted of 25 cases that intake 200 mg of colofac capsule twice a day for 3 month.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoolakram Hospital

Full name of responsible person

Dr Shahram Agah

Street address

Shahrara; Nyayesh Ave.; Sattarkhan Str.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research Traditional Medicine
Faculty of Tehran University of Medica

Full name of responsible person
Mohamad Bagher Minaei

Street address
Behesht Street, Vahdat eslami Ave.

City
Tehran

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 Traditional Medicine Faculty
of Tehran University of Medica

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
Traditional Medicine Faculty, Tehran University of
Medical Sciences

Full name of responsible person
Mostafa Salehi Nagaf Abadi

Position
PhD candidate

Other areas of specialty/work

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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