

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of oral administration of Carum Copticum product compared to placebo in reducing symptoms of bloating and flatulence

Protocol summary

Summary

This study evaluates the effects of oral administration of Carum Copticum product compared to placebo in reducing symptoms of bloating and Flatulence. This is a randomized, double-blind (meaning that neither the patients nor the researchers know who is getting a placebo and who is getting the treatment), placebo-controlled, phase one study. The study is done in Hazrate Rasule Akramh (PBUH) Hospital as well as the private clinics of gastroenterology. Inclusion criteria: age of 18 to 49 years, symptoms of flatulence, bloating or feeling of abdominal distention, normal abdominal examination, normal blood and stool tests. Exclusion criteria: History of chronic or structural disorders of the gastrointestinal tract, serious clinical conditions, diabetes, thyroid gland disease, serious systemic disease, uncontrollable high blood pressure, major psychiatric disorders, diagnosis of lactase deficiency or relieving symptoms by lactase free diet, alarm signs, gastrointestinal surgery, masticatory disorders, cancer, drugs affecting the movement of the digestive tract two weeks before and during the study, taking antibiotics one month before starting the study, drug or alcohol abuse, lactating and pregnant women. Sample size would be 108 patients. The intensity and frequency of the symptoms including bloating, belching, abdominal sounds, abdominal pain, flatulence, flatus incontinence as well as possible drug side effects will be obtained for each patient in three times including the admission phase, four weeks after treatment and four weeks after finishing the treatment. Symptoms will be assessed using the Likert scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091614679N1**

Registration date: **2013-11-08, 1392/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-08, 1392/08/17

Registrant information

Name

Maryam Yazdian

Name of organization / entity

Traditional Medicine Faculty of Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2612 3341

Email address

ma_yazdian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral administration of Carum Copticum product compared to placebo in reducing symptoms of bloating and flatulence

Public title

Carum Copticum effect in the treatment of bloating

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 49 years, symptoms of flatulence, bloating or feeling of abdominal distention in the last three months with symptom onset at least six months prior to the study, normal abdominal examination, normal blood and stool tests including CBC, ESR, TSH, Ca, P, ALT, AST, Alph, BUN, Cr, FBS, TTGA, Stool exam (OB, OP, Leukocyte). Exclusion criteria :History of chronic or structural disorders of the gastrointestinal tract such as irritable bowel disease, peptic or duodenal ulcer disease, gastrointestinal obstruction, symptomatic gallbladder stone, serious clinical conditions, diabetes, thyroid gland disease, serious systemic disease (including heart , renal , lung and liver failure), uncontrollable high blood pressure, major psychiatric disorders, diagnosis of lactase deficiency or relieving symptoms by lactase free diet, alarm signs such as involuntarily weight loss more than 4.5 kg in the last three months, blood detection in the stool or melena or hemoptysis in the last three months, gastrointestinal surgery other than appendectomy, Hernioplasty, inguinal, abdominal wall surgery, cesarean section, hysterectomy and tubal ligation, masticatory disorders, cancer, drugs affecting the movement of the digestive tract such as surfactants, antispasmodic, osmotic laxatives, bulking agents, dopamine antagonists, muscarinic antagonist, 5HT4 and 5HT1 and 5HT3 agonists, antibiotics, opioids, anti-diarrheal medication, symbiotics, antimetotics (eg colchicine), anticholinergics, narcotics, antidepressants, anticonvulsants and any antifatulence herbal medication two weeks before and during the study, taking antibiotics one month before starting the study, drug or alcohol abuse, lactating and pregnant women.

Age

From **18 years** old to **49 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In a double-blind, placebo-controlled clinical trial, neither the patients nor the researchers know who is getting a placebo and who is getting the treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No.9, Pirnya Alley, Lalezar St., Jomhoori St.

City

Tehran

Postal code

Approval date

2013-02-03, 1391/11/15

Ethics committee reference number

1056/پ-26/م/ط

Health conditions studied

1

Description of health condition studied

bloating

ICD-10 code

K31

ICD-10 code description

Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description

bloating, abdominal pain, flatulence, eructation, borborygmi, gas incontinence

Timepoint

before intervention, one month after starting the trial, one month after the end of trial

Method of measurement

Likert scale

Secondary outcomes

1

Description

side effects

Timepoint

one month after starting the trial

Method of measurement

questionnaire

Intervention groups

1

Description

Control group:Our placebo is corn starch oral capsules which should be taken three times daily,one capsule after every meal for a month

Category

Placebo

2

Description

Intervention group:Our drug is carum capticum seed oral capsules which should be taken three times daily,one capsule after every meal for a month

Category

Treatment - Drugs

3

Description

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Holy Prophet (PBUH) Hospital

Full name of responsible person

Doctor Shahram Agah

Street address

Nyayesh St., Sattarkhan St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Doctor Masoud Younesian

Street address

6th Floor, Central building of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

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 of 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

Vice chancellor for research of Traditional Medicine Faculty of Tehran University of Medical Science

Full name of responsible person

Maryam Yazdian

Position

Resident

Other areas of specialty/work

Street address

South side of City Park, Behesht St., Vahdate Eslami St.

City

Tehran

Postal code

Phone

+98 21 5569 3520

Fax

Email

ma_yazdian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Traditional Medicine Faculty of Tehran University of Medical Sciences

Full name of responsible person

Doctor Bagher Minaye

Position

Assistant Professor

Other areas of specialty/work

Street address

South side of City Park, Behesht St., Vahdate Eslami St.

City

Tehran

Postal code

Phone

+98 21 5560 1274

Fax

Email

minaebz@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Traditional Medicine Faculty of Tehran University of
Medical Sciences

Full name of responsible person

Maryam Yazdian

Position

Traditional Medicine Resident

Other areas of specialty/work**Street address****City****Postal code****Phone****Fax****Email****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