Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The effect of Kaaser capsule (Zingiber Officinale, Carum Capticum, Piper Nigrum) on functional bloating and comparison with Dimethicone capsule; Clinical Control Trial.

Protocol summary

Summary

The purpose of the study is to compare the effect of "Kaaser" capsule (Zingiber Officinale, Carum Capticum, Piper Nigrum) with Dimethicone capsule and placebo on functional bloating. One hundred twenty 20-50 years old patients who recourse Ayatollah Rouhani hospital with considering inclusion and exclusion criteria, will enter the study. Enrolling in 3 groups of "Kaaser" capsule, Dimethicone capsule, and placebo cases will be done with simple sampling and random allocation. Design and performance of the study are double blind.The cases are obtained written informed consent and will explain them that enrolling in the groups is randomly.The forms of demographic information will be completed and also severity and frequency of bloating and early satiety (based on Visual Analogue Scale) before enrolling in to the study.Drugs in 3 groups will given in 500 mg capsules TDS.Severity and frequency of Bloating will evaluated,2weeks after starting the study and 2 weeks and 2 months after finishing the study. And early satiety will evaluate 2 weeks of starting the study and those will written and compared with the baseline data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100324327N1**
Registration date: **2016-01-13, 1394/10/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-13, 1394/10/23

Registrant information

Name

Zeinab Mahmoudpour

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol university of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Kaaser capsule (Zingiber Officinale, Carum Capticum, Piper Nigrum) on functional bloating and comparison with Dimethicone capsule; Clinical Control Trial.

Public title

The effect of of Kaaser capsule (Zingiber Oficinale, Caum Capticum, Piper Nigrum) on bloating.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 20 to 50 years, symptoms of bloating: feeling of abdominal distention, increasing of abdominal gas in the last three months with symptom onset at least six months prior to the study, three days a week; Exclusion criteria :I.B.D on colonoscopy, Diabetes, Anemia, Hypothyroidism, Celiac, Kidney disease,use of any treatment of bloating on during the study.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

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
Ethics Committee of Babol university of medical science Ethics.

Street address
Babol- Ganjafrooz street- university of Babol

City
Babol

Postal code
47745-47176

Approval date
2015-12-06, 1394/09/15

Ethics committee reference number
MUBABOL.REC.1394.233

Health conditions studied

1

Description of health condition studied
Bloating

ICD-10 code
R14

ICD-10 code description
Flatulence and related conditions

Primary outcomes

1

Description
severity of bloating

Timepoint
before study, two weeks after starting the study, two weeks and two months after finishing the study

Method of measurement
Visual Analogue Scale

2

Description
Frequency of bloating

Timepoint
Befor study,two weeks after starting the study,two weeks and two mounths after finishing the study

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Early satiety

Timepoint
2 weeks afrer starting the study

Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group 1: Kaaser capsule (Zingiber Officinae, Carum Copticum, Piper Nigrum), 500 mg, TDS, 2 weeks.

Category
Treatment - Drugs

2

Description
Intrventional group2:Dimethicone capsul consisted of 40mg Dimethicone,TDS,2 weeks

Category
Treatment - Drugs

3

Description
Interventional group3:Placebo capsul,500mg,TDS,2weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of Ayatollah Roohani hospital in Babol

Full name of responsible person
Dr Neda Meftah, Dr Zeinab Mahmoudpour

Street address

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Babol university of Medical Sciences

Full name of responsible person
Dr Ali Bijani

Street address
Ganjafrooz street, Babol

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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, Babol 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
Babol university of medical sciences

Full name of responsible person
Zeinab Mahmoudpour

Position
Student

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