Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assesing the effect of combination of cumin, caraway, coriander and mint on symptoms of gastritis

Protocol summary

Study aim
Determining the effect of combination of cumin, caraway, coriander and mint on symptoms of gastritis
Design
80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table
Settings and conduct
This double blinded study will be performed in Fayaz Bakhsh Hospital. At base line Patient Assessment of Gastrointestinal Health questionnaire will be completed for each patient. after 2 weeks of intervention with supplement/placebo patients will complete the questionnair again.
Participants/Inclusion and exclusion criteria
Inclusion critaria: Having constipation diagnosed by internist, age between 18-65 years old, Willing to participate Exclusion critaria: Pregnancy and lactation, Having known kidney disease, Having any type of cancer, Having gastrointestinal bleeding, Having known heart disease
Intervention groups
Patients will receive 500 mg cumin, caraway, coriander and mint (®Rugastrin, Ghaem Darou) or placebo 2 times daily, after lunch and dinner, each time 2 capsule for 2 weeks. Placebo capsule contain maltodextrine.
Main outcome variables
Gastrointestinal Health questionnaire score changes (Including 4 sections: gastric function, GI inflammation, Small intestin & pancreas, and Colon)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20140804018677N18**
Registration date: **2022-05-07, 1401/02/17**
Registration timing: **registered_while_recruiting**
Last update: **2022-05-07, 1401/02/17**
Update count: **0**
Registration date
2022-05-07, 1401/02/17

Registrant information
Name
soodeh razeghi Jahromi
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2022-08-23, 1401/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assesing the effect of combination of cumin, caraway, coriander and mint on symptoms of gastritis

Public title
Effect of combination of cumin, caraway, coriander and mint on symptoms of gastritis
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Having constipation diagnosed by internist age between 18-65 years old Willing to participate
Exclusion criteria:
Pregnancy and lactation Having known kidney disease Having any type of cancer Having gastrointestinal bleeding Having known heart disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

Blinding (investigator's opinion)
Double blinded

Blinding description
It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of research and technology deputy of Shahid Beheshti University of Medical Sciences

Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City
Tehran

Province
Tehran

Postal code
1981619573

Approval date
2022-02-20, 1400/12/01

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.940

Health conditions studied

1

Description of health condition studied
Gastritis

ICD-10 code
K29.7

ICD-10 code description
Gastritis, unspecified

Primary outcomes

1

Description
Gastrointestinal function

Timepoint
Baseline and at the end of the study

Method of measurement
Gastrointestinal Health Assessment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 500 mg capsules contains cumin, caraway, coriander and mint (Ghaem darou company), BD, 2 Cap each time for 2 weeks

Category
Treatment - Other

2

Description
Control group: Placebo contain maltodextrine (500 mg), Ghaem darou company, BD, 2 Cap each time for 2 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Fayaz Bakhsh Hospital
Full name of responsible person
Soodeh Razeghi Jahromi
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
No. 7, West Arghavan St., Farahzadi Blv., Qods Town
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Soodeh Razeghi Jahromi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data would be available to public

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
To all

Under which criteria data/document could be used
No other criteria

From where data/document is obtainable
Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document
sending email to me

Comments