Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of anti-flatulence effects of ZAX capsule in comparison with dimethicone in patients with bloating: A crossover clinical trial

Protocol summary

Study aim
Anti-flatulence efficacy of ZAX capsule against Dimethicone

Design
Both groups will not receive any medication for a week during the washout period. Then the two groups will be crossed, so that for another 2 weeks, group one (400 mg ZAX capsule and dimethicone 40 mg placebo after each meal) and group two (dimethicone 40 mg tablet and ZAX capsule placebo) Will receive 400 mg after each meal. Patients in the second, fourth and eighth weeks after the end of the study will be evaluated for changes in symptoms.

Settings and conduct
1- Patient and disease profile checklist 2- Rome IV questionnaire to assess gastrointestinal disorders and a questionnaire based on the severity and frequency of bloating and related symptoms 3-Satisfaction with treatment with general questions and at the end of the study patients are asked. 4- Abdominal circumference is measured with a meter. 5- Stool excretion is measured on a Bristol scale. Gastroenterology and Liver Research Center, Golestan Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Existence of symptoms related to bloating, in at least the last three months and with the onset of symptoms at least six months ago; Frequent bloating at least one day a week (moderate to severe bloating intensity); Normal abdominal examinations Exclusion criteria: Lactose intolerance; Existence of danger signs and the presence of blood in the stool or melena or bloody vomit in the last three months

Intervention groups
In the group 1, patients will receive dimethicone tablet (40 mg) and placebo of ZAX capsule (400 mg) for 2 weeks. In the group 2, patients will receive ZAX capsule (400 mg) and placebo of Dimethicone tablet (40 mg) for 2 weeks.

Main outcome variables
The primary consequence of the severity and frequency of bloating and the symptoms associated with bloating

General information

Reason for update

Acronym
GBS

IRCT registration information
IRCT registration number: **IRCT20110907007511N5**
Registration date: **2021-08-03, 1400/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-03, 1400/05/12**
Update count: **0**

Registration date
2021-08-03, 1400/05/12

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of anti-flatulence effects of ZAX capsule in comparison with dimethicone in patients with bloating: A crossover clinical trial

Public title
Anti-flatulence effects of ZAX capsule in treatment of bloating
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Conscious consent to participate in the study Symptoms of bloating include a feeling of bloating or visible abdominal distention in at least the last three months and with the onset of symptoms at least six months ago Frequent bloating at least one day a week (moderate to severe bloating intensity) Normal abdominal examinations Normal colonoscopy in people over 50 years of age in the last year before entering the study No irritable bowel syndrome, functional constipation, functional indigestion or other gastrointestinal dysfunction Normality of tests: CBC, ESR TSH, Ca, P and Stool exam for leukocyte, OB, OP (parasite in feces, occult blood and leukocytes) and AST, ALT, ALP, BUN, Cr, FBS TTGA (IgA) (for celiac disease).)
Exclusion criteria:
Pregnant or lactating women Sensitivity to one of the herbs that make up the product History of chronic inflammation or structural disorders of the gastrointestinal system such as IBD, known peptic or duodenal ulcer, gastrointestinal obstruction or symptomatic gallstones Chronic diseases such as diabetes, thyroid dysfunction and uncontrollable hypertension Serious systemic disease (heart, kidney, lung and liver failure) Lactose intolerance (lactase deficiency) Dangerous symptoms such as involuntary weight loss of more than 4 kg in the last three months and blood in the stool or melena or bloody vomiting in the last three months History of gastrointestinal surgery other than appendectomy, inguinal hernia or abdominal wall, cesarean section, hysterectomy and tubal ligation Cancer Use of drugs affecting gastrointestinal motility (such as surfactants, antispasmodics), laxatives and any herbal anti-flatulence medication in the two weeks before the study Take antibiotics one month before the start of the study Substance or alcohol abuse
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The random assignment list will be computer generated with a 1: 1 allocation, stratified by recruitment site, using random block sizes of four. Using concealed in sequentially numbered, sealed, opaque envelopes (SNOSE), participants will enter the blocks in such a way that an equal number of each assigned group. Allocation will be done by randomly selecting one of the arrangements and assigning the next part of the participants to the study groups according to the specified sequence. And kept by the hospital pharmacist of the center.
Blinding (investigator's opinion)
Double blinded
Blinding description
To maintain blindness in patients, since the two drugs ZAX and Dimethicone are not identical in appearance, a placebo of both drugs is made, which is considered as the drug in terms of shape and appearance; In this way, one group will receive ZAX capsules and placebo of Dimethicone tablets and the other group will receive Dimethicone tablets along with placebo of ZAX capsules. In fact, each treatment group contains a drug package containing 2 drug forms (capsules and tablets). Also, the evaluator is not aware of the type of drugs in the intervention groups, so that multi-digit numeric codes (barcodes) are written on the drug packages that only the main person in charge of the research knows about them and can access the codes if needed. And the type of drug is determined.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Golestan University of Medical Sciences
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Shast-Kolah Road
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4934174515
Approval date
2021-05-31, 1400/03/10
Ethics committee reference number

IR.GOUMS.REC.1400.062

Health conditions studied

1

Description of health condition studied
Functional bloating
ICD-10 code
R14.0
ICD-10 code description
Abdominal distension

Primary outcomes

1

Description
the severity of bloating
Timepoint
1. Time 0: The beginning of the study (face-to-face visit)2. Time 1: Two weeks after receiving the drug of stage 1 (face-to-face visit)3. Time 2: End of stage 1 drug course and one week washout, cross-sectional study and start of stage 2 drug treatment and reuse of drugs (face-to-face visit)4. Time 3: 2 weeks after receiving stage 2 medication (face-to-face visit)5. Time 4: First follow-up - 2 weeks after the end of the drug (telephone follow-up)6. Time 5: Second follow-up - 4 weeks after the end of the drug (telephone follow-up)7. Time 6: Third follow-up - 8 weeks after the end of the drug (face-to-face visit)
Method of measurement
face-to-face visits and telephone follow-up

2

Description
the frequency of bloating
Timepoint
1. Time 0: The beginning of the study (face-to-face visit)2. Time 1: Two weeks after receiving the drug of stage 1 (face-to-face visit)3. Time 2: End of stage 1 drug course and one week washout, cross-sectional study and start of stage 2 drug treatment and reuse of drugs (face-to-face visit)4. Time 3: 2 weeks after receiving stage 2 medication (face-to-face visit)5. Time 4: First follow-up - 2 weeks after the end of the drug (telephone follow-up)6. Time 5: Second follow-up - 4 weeks after the end of the drug (telephone follow-up)7. Time 6: Third follow-up - 8 weeks after the end of the drug (face-to-face visit)
Method of measurement
the frequency of bloating

Secondary outcomes

1

Description
Satisfaction of treatment
Timepoint
the end of the study
Method of measurement
questionnaire

Intervention groups

1

Description
Group 1 will receive Dimethicone chewable tablets 40 mg and placebo of Zax capsules 400 mg after each meal for 2 weeks. They will not receive any medication for a week during the washout period. They will then be crossed, receiving for another 2 weeks Zax capsule 400 mg and placebo of Dimethicone 40 mg after each meal. Dimethicone is provided by Sobhan Daroo Company.
Category
Treatment - Drugs

2

Description
Group 2 will receive Zax capsule 400 mg and placebo of Dimethicone 40 mg after each meal. They will not receive any medication for a week during the washout period. They will then be crossed, receiving for another 2 weeks, Dimethicone chewable tablets 40 mg and placebo of Zax capsule 400 mg after each mea. Zax capsules are manufactured by NIAK Company. After collection, the plants are divided into smaller pieces and after drying separately in the shade, they are pulverized by an electric mill. The plants were mixed with the specified ratios (Dry extract of apricots: 25%, dry extract of thyme: 25%, frankincense: 25%, dry extract of black seed: 17.5%, magnesium stearate 0.25%, aerosil 0.75%, starch 6.5%) and finally a capsule with a filled weight of 400 mg was prepared in the filling section without pus. The standardization of the capsule with 3.67 mg of thymol in each capsule was done by spectrophotometric method according to the German Pharmacopoeia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

Sponsor
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https://niakpharma.com/index.php/en/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Niak Pharmaceutical Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available