

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of Ardor syrup on the severity of functional bloating in the elderly

Protocol summary

Study aim

Determining the effect of Ardor syrup on the severity of functional bloating in the elderly

Design

Clinical trial with a control group, with a parallel group, double-blind, randomized, phase 3 on 72 patients for 4 weeks.

Settings and conduct

Samples that meet the inclusion criteria will be selected from those who refer to the specialized clinics of Mazandaran University of Medical Sciences located in Sari city, and the block method will be used to allocate the samples. 12 blocks of 6 will be created and the samples will be assigned to each of the blocks and groups accordingly. It should be noted that three samples from the drug group and three samples from the placebo group will be placed in each block

Participants/Inclusion and exclusion criteria

- People older than 60 years, whose Functional bloating has been confirmed by a Gastroenterologist based on Rome III criteria - Consent of the individual for voluntary participation in research - History of takes Anti H. pylori medicine in the last tree months - Patients with a History of stomach or intestinal surgery - Patients with diabetes or severe mental illness - Patients who take antibiotics - History of allergy to Herbal medicines

Intervention groups

Ardor syrup group Placebo syrup group

Main outcome variables

Intensity of bloating

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230316057734N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **prospective**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Mokhtar Hedayati

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3330 9082

Email address

m@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Ardor syrup on the severity of functional bloating in the elderly

Public title

The effect of Ardor syrup on the severity of functional bloating in the elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People older than 60 years, whose Functional bloating has been confirmed by a Gastroenterologist based on Rome III criteria Consent of the individual for voluntary participation in research

Exclusion criteria:

History of taking Anti H. pylori medicine in the last tree months. Patients with a History of stomach or intestinal surgery Patients with diabetes or severe mental illness Patients who take antibiotics History of allergy to Herbal medicines

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the samples will be determined and the blocking method will be used to allocate the samples. This process will be done with Random allocation software. With this software, 12 block of 6 will be created and the samples will be assigned to each of the blocks and groups accordingly. It should be noted that three samples from the drug group and three samples from the placebo group will be placed in each block with A or B signs.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medicines and placebos will be prepared in the same color and packaging bottle, and before the intervention will be coded by a statistical expert cooperater, so that the researcher and the patient will not know the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical

Sciences

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Teacher Street, Teacher's Square

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.MAZUMS.REC.1402.114

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

Intensity of bloating

Timepoint

Measuring the intensity of bloating before the study (day zero), 7, 14, 21, 28

Method of measurement

7-point Likert scale (Gastrointestinal symptom severity questionnaire)

Secondary outcomes

1

Description

Number of bowel movements

Timepoint

The day before starting the study (day zero), 7, 14, 21, 28

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Arder syrup, 5 cc every 12 hours until one hour after meals. (Arder syrup consists of Pimpinella anisum seed, Foeniculum vulgare seed, Apium graveolens seed, Rosa damascene petal and Crocus

sativus stigma.

Category

Treatment - Drugs

2

Description

Control group: Placebo syrup, will be prepared in the same color and container as drug syrup, 5 cc every 12 hours until one hour after meals.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari, specialized clinic of Mazandaran University of Medical science

Full name of responsible person

Asieh Jokar

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Pasdarán Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Omran Habibi

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Moalem St. Research and Technology Vice-Chancellor of Mazandaran University of Medical Sciences

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Asieh Jokar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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