

# 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)

###### Phone

+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

**Street address**

Pasdarán Blvd

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 3014

**Email**

a.jokar@mazums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Omran Habibi

**Street address**

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

**City**

Sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**Phone**

+98 11 3325 7230

**Email**

pajhooheshi@mazums.ac.ir

**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

**Street address**

Traditional and Complementary Medicine Research Center of Mazandaran University, Khazar Blvd, Khazar Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

48168-95475

**Phone**

+98 11 3324 4893

**Email**

a.jokar@mazums.ac.ir

**Person responsible for scientific 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

**Street address**

Traditional and Complementary Medicine Research Center of Mazandaran University, Khazar Blvd, Khazar Square

**City**

Sari  
**Province**  
Mazandaran  
**Postal code**  
4816895475  
**Phone**  
+98 11 3324 3117  
**Email**  
a.jokar@mazums.ac.ir

Mazandaran  
**Postal code**  
48168-95475  
**Phone**  
+98 11 3310 9650  
**Email**  
dr.m.acur@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Mokhtar Hedayati  
**Position**  
Persian Medicine student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
Traditional and Complementary Medicine Research  
Center of Mazandaran University, Khazar Blvd, Khazar  
Square  
**City**  
Sari  
**Province**

## 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