Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the effectiveness of adding an antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate to a proton pump inhibitor for improving epigastric pain or burning, early satiety, and postprandial fullness in patients over 18 with functional dyspepsia versus placebo: A randomized clinical trial

Protocol summary

Study aim
Assessing the effectiveness of adding an antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate to a proton pump inhibitor for improving epigastric pain or burning, early satiety, and postprandial fullness in patients with functional dyspepsia

Design
A randomized, double-blind, controlled, parallel-group phase 3 clinical trial on 50 patients

Settings and conduct
This study will be conducted on patients over 18 years of age with functional dyspepsia who visit Imam Khomeini hospital. The first group will receive the standard treatment regimen, consisting of a once-daily proton pump inhibitor, along with a placebo. The second group will receive the standard treatment together with an antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate, to be taken four times a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 18 years old with functional dyspepsia. Exclusion criteria: Pregnancy, breastfeeding, patients who have received a Helicobacter pylori eradication regimen containing a proton pump inhibitor within the last 28 days or who have had a positive H. pylori stool antigen test, individuals with renal, heart, or liver failure, and patients who have taken medications affecting gastric acid within the past 14 days.

Intervention groups
In the control group, 25 adult patients with functional dyspepsia will receive a proton pump inhibitor as the standard treatment, along with a placebo. In the experimental group, 25 adult patients with functional dyspepsia will receive the standard treatment (a proton pump inhibitor) in addition to a tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate.

Main outcome variables
The severity and frequency of: epigastric burning or pain, early satiety, and postprandial fullness.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230629058615N10**
Registration date: **2025-09-09, 1404/06/18**
Registration timing: **prospective**

Last update: **2025-09-09, 1404/06/18**
Update count: **0**

Registration date
2025-09-09, 1404/06/18

Registrant information
Name
Amir Rezazadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01
Expected recruitment end date
2026-05-22, 1405/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effectiveness of adding an antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate to a proton pump inhibitor for improving epigastric pain or burning, early satiety, and postprandial fullness in patients over 18 with functional dyspepsia versus placebo: A randomized clinical trial

Public title
Assessing the effectiveness of adding an antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate to proton pump inhibitors in patients with functional dyspepsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with functional dyspepsia based on the Rome IV criteria Patients over 18 years old Patients who have filled out an informed consent form and are aware of the study process
Exclusion criteria:
Pregnant and lactating women Patients with renal failure (GFR<30), liver failure (Child Pugh B, C), or heart failure (NYHA class 3, 4) Patients who received a Helicobacter pylori eradication regimen containing a proton pump inhibitor within the last 28 days, and individuals with a positive H. pylori stool antigen test within the last 28 days Individuals who have taken any of the following medications within the past 14 days: Sucralfate, Misoprostol, Proton pump inhibitors, H2-receptor antagonists, Antacids, Prokinetics, Anticholinergics, Glucocorticoids, or Non-steroidal anti-inflammatory drugs (This excludes aspirin at a dose of less than 325 mg for cardiovascular disease prevention) Individuals with a history of the following: gastrointestinal surgery, significant cardiopulmonary, metabolic, hematologic, hepatic, renal, neurologic, and psychiatric disorders, malignancy, gastrointestinal ulcers and obstructions, history of peptic ulcer, reflux esophagitis, and Barrett's or erosive esophagitis within the past 6 months People with uncontrolled diabetes (HbA1c >8% and fasting blood glucose> 180 mg/dl) or uncontrolled blood pressure (blood pressure > 160/100 mmHg) Patients with dyspepsia whose symptoms are relieved by defecation or are associated with a change in the frequency or consistency of their stool
Age
From **18 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
In this study, volunteers were individually assigned to two groups (medication and placebo) using block randomization. Notably, 4-block randomization was used in this method. The block randomization is performed using the website https://www.sealedenvelope.com/simple-randomiser/v1/lists, and the obtained unique codes (consisting of two English letters and one number) are assigned to each volunteer in the order of their entry into the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
An independent individual performs the block randomization and numbers the medications and placebos based on the codes generated. The study's physician and executive only provide the patients with the medication or placebo based on each person's code and are unaware of the drug type. Likewise, the patients receive their coded medication and are unaware of their treatment type. Notably, the statistical analyst is not blinded to the groups and uses information from the aforementioned independent individual to assign patients to two groups and apply the statistical tests.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Research Ethics Committees of Pharmacy and Pharmaceutical Sciences- Islamic Azad University
Street address
No. 99, Yasaman St., Yakhchal St, Shariati Ave.
City
Tehran
Province
Tehran
Postal code
1941933111
Approval date
2025-08-19, 1404/05/28

Ethics committee reference number
IR.IAU.PS.REC.1404.328

Health conditions studied

1

Description of health condition studied
Functional dyspepsia
ICD-10 code
K30
ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
The severity and frequency of epigastric pain
Timepoint
Before starting the study and 14 days after the start of the study.
Method of measurement
The Short Form Nepean Dyspepsia Index Questionnaire

2

Description
The severity and frequency of epigastric burning
Timepoint
Before starting the study and 14 days after the start of the study.
Method of measurement
The Short Form Nepean Dyspepsia Index Questionnaire

3

Description
The severity and frequency of early satiety
Timepoint
Before starting the study and 14 days after the start of the study.
Method of measurement
The Short Form Nepean Dyspepsia Index Questionnaire

4

Description
The severity and frequency of postprandial fullness
Timepoint
Before starting the study and 14 days after the start of the study.
Method of measurement
The Short Form Nepean Dyspepsia Index Questionnaire

5

Description
The severity and frequency of epigastric pain
Timepoint
Before starting the study and 3 days after the start of the study
Method of measurement
The Visual Analogue Scale with a score from one to ten

6

Description
The severity and frequency of epigastric burning
Timepoint
Before starting the study and 3 days after the start of the study
Method of measurement
The Visual Analogue Scale with a score from one to ten

Secondary outcomes

1

Description
Side effects of antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate
Timepoint
14 days after the start of the study.
Method of measurement
Questioning the patient

2

Description
Improving the quality of life of patients receiving antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate in addition to a standard treatment
Timepoint
Before starting the study and 14 days after the start of the study.
Method of measurement
The Short Form Nepean Dyspepsia Index Questionnaire

Intervention groups

1

Description
The intervention group: It consists of 25 patients who, after meeting the study's inclusion and exclusion criteria and providing informed consent, will receive an antacid tablet containing sodium alginate, sodium bicarbonate, and calcium carbonate, produced by Tamin Salam Arapharmed pharmaceutical company. The tablets will be administered four times a day. This is in addition to their standard treatment (a proton pump inhibitor once daily). The treatment duration is 14 days. Patients will be evaluated at three time points: before the study begins, and at 3 and 14 days after the start of treatment.
Category
Treatment - Drugs

2

Description
The control group: It consists of 25 patients who, after

meeting the study's inclusion and exclusion criteria and providing informed consent, will receive standard treatment (a proton pump inhibitor once daily) and a placebo, produced by Tamin Salam Arapharmed pharmaceutical company, four times daily. The treatment duration is 14 days. Patients will be evaluated at three time points: before the study begins, and at 3 and 14 days after the start of treatment.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Setare Abolghasemi

Street address
Valiasr square, end of Keshavarz boulevard, Dr. Gharib street

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6119 0000

Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Amirhossein Abdolghaffari

Street address
No. 99, Yakhchal Street, Shariati Avenue.

City
Tehran

Province
Tehran

Postal code
1916893813

Phone
+98 21 2264 0599

Email
amirhosein172@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tamin Salam Arapharmed 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
Islamic Azad University

Full name of responsible person
Setare Abolghasemi

Position
Pharmacy Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

Street address
No. 99, Yasaman St., Yakhchal St, Shariati Ave.

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Tehran

Province
Tehran

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1941933111

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sohaabolghasemi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Amir Rezazadeh

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Shahid basarati St, shahid kabiri tameh (shahin Shomali) St, Hemmat Highway

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Tehran

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Tehran

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1475886671

Phone

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Email

rezazadeh.am@ius.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kamyab Andarzbakhsh

Position

Clinical cooperator of the study

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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No. 99, Yasaman St., Yakhchal St, Shariati Ave.

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Kamyab.dr@gmail.com

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

The final results of scoring the relevant parameters based on the questionnaire.

When the data will become available and for how long

After publishing the related article in international journals.

To whom data/document is available

Researchers in the field of medicine and pharmacy

Under which criteria data/document could be used

Development of science and expand evidence related to treatment in further research

From where data/document is obtainable

Islamic Azad University, Tehran Medical Sciences Branch: Respected applicants can use the following method to receive their desired documents or data from Islamic Azad University, Tehran Medical Sciences Branch: Communication with the Research and Technology Unit: To receive information and documents related to research and clinical trials, applicants can refer to the Research and Technology Unit of the university. Postal Address: Administrative Building Address: Administrative Building of Tehran Islamic Azad University of Medical Sciences, Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Qolhak, Dr. Shariati Street, Tehran, Iran. Contact Number: 26602642-3 Email: rezazadeh.am@ius.ac.ir Website: www.tms.iau.ir

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

Request Submission and Documentation/Data Retrieval Process from the Research and Technology Department: Request Submission: Applicants must submit their request in writing, including full details (type of documents or data, purpose of request, and related supplementary information) to the university's Research and Technology Department. Method of Submission: Requests can be delivered in person to the Research and Technology Department. Postal Address: Administrative Building Address: Administrative Building of Tehran Islamic Azad University of Medical Sciences, Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Qolhak, Dr. Shariati Street, Tehran, Iran. Phone Number: 26602642-3. Request Review: After receiving the request, the Research and Technology Department staff will review it. This review includes assessing the content of the request and determining if additional information is needed. If further clarification or adjustments are required, the applicant will be contacted via email or phone. Document/Data Delivery: Once prepared, the requested documents or data will be delivered to the applicant either in person or electronically. Delivery Methods: Electronic: Sent via email. Final Delivery Timeframe: 1 to 2 business days after preparation.Follow-up and Communication: Applicants can contact the Research and Technology Department at any stage of the process to follow up on the status of their request. Phone Number: 26602642-3. Estimated Overall Timeframe for Receiving Documents/Data: From the time the request is submitted until the final receipt of documents or data, the process typically takes between 15 and 20 business days.

Comments