

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the therapeutic effect of alkaline water in patients with gastroesophageal reflux disease

Protocol summary

Study aim

Determination of the effect of alkaline water in patients with gastroesophageal reflux disease

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients with gastroesophageal reflux disease referred to Imam Ali Clinic and Prophet Rasul Clinic in Shahrekord will selected by convenience sampling and will randomly divided into two intervention and control groups of 36 each. The intervention group received alkaline water and the control group received ordinary mineral water. Gastrointestinal symptoms before and 6 weeks after the study will be assessed by the Gastrointestinal Symptom Rating Scale (GSRS).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Symptoms of gastroesophageal reflux disease at least 2 times a week for at least 3 months; Age between 18 to 40 years; Exclusion criteria: Any pathological problem associated with gastroesophageal reflux disease including Barrett's esophagus and malignancy; Having warning signs such as painful and difficulty swallowing, nausea, vomiting and fever

Intervention groups

Intervention group will receive at least 1.3 liters of alkaline water (bottle A) daily regardless of specific consumption pattern and based on routine consumption. The control group will receive 1.3 liters of ordinary mineral water (bottle B) daily.

Main outcome variables

Changes in gastrointestinal symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042935N2**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **retrospective**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Abdolrahim Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-31, 1398/03/10

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of alkaline water in patients with gastroesophageal reflux disease

Public title

Effect of alkaline water in treatment of gastroesophageal reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptoms of gastroesophageal reflux disease at least 2 times a week for at least 3 months Age between 18 to 40 years

Exclusion criteria:

Any pathological problem associated with gastroesophageal reflux disease including Barrett's esophagus and malignancy Having warning signs such as painful and difficulty swallowing, nausea, vomiting and fever

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Convenience sampling will be done. To this end, 72 cards of the same size and shape will be labelled A and B one by one, and then patients will randomly pick one card in order of their enrollment in the study and will be assigned to either group according to the label of the card they picked.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study considering the use of similar bottles in all two groups, participants, researcher and the assessor, are not aware of the contents of the bottles and the groups will be checked with the names A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Research Deputy, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2018-10-07, 1397/07/15

Ethics committee reference number

IR.SKUMS.REC.1397.122

Health conditions studied

1

Description of health condition studied

Gastroesophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Mean scores of gastrointestinal symptoms in GERD questionnaire

Timepoint

Before the intervention and six-week after intervention

Method of measurement

Gastroesophageal Reflux Disease (GERD) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive at least 1.3 liters of alkaline water (bottle A) daily regardless of specific consumption pattern and based on routine consumption. For the preparation of alkaline water, ordinary mineral water is contacted with the catalyst and collected in a bottle and provided to the patient.

Category

Treatment - Drugs

2

Description

Control group: This group will receive 1.3 liters of ordinary mineral water (bottle B) daily regardless of specific consumption pattern and based on routine consumption.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Clinic of Shahrekord

Full name of responsible person

Doctor Ghorbanali Rahimian

Street address

Emam Ali Clinic of Shahrekord, Shariati Street

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2

Recruitment center

Name of recruitment center

Prophet Rasul Clinic in Shahrekord

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Deputy of Research and Technology, Shahrekord University of Medical Sciences, Ayatollah Kashani Blvd.

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Grant name

Grant code / Reference number

2796

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Doctor Ghorbanali Rahimian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Gastroenterology and Hepatology

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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

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

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