

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of Shirazi thyme essential oil on the clinical symptoms of patients with gastroesophageal reflux disease

#### Protocol summary

##### Study aim

Determining the effect of Shirazi thyme essential oil on the clinical symptoms of patients with gastroesophageal reflux

##### Design

A clinical trial with a control group, with parallel groups, without blinding, randomization, phase 3, on 70 patients, was used to randomize the table of random numbers.

##### Settings and conduct

The present study is a two-group randomized clinical trial. The patients with gastroesophageal reflux referring to Allameh Bahloul Gonabadi Hospital, Gonabad City, are the studied community. After obtaining informed consent, the demographic questionnaire and the reflux disease questionnaire will be distributed among the samples and completed by them. In the control group, no intervention is performed for the patients, and for these patients, educational and therapeutic measures are performed normally. In the intervention group, two gastrolith capsules containing Shirazi thyme essential oil are given to the patients after lunch and dinner for 6 weeks. After the end of the study, the patients will complete the reflux disease questionnaire again and finally the collected data will be analyzed using SPSS version 22 software.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 20 and 60 years old with second-degree gastroesophageal reflux disease who were unable to resolve the symptoms with lifestyle changes. And they did not have gastrointestinal bleeding or surgery during the study. Exclusion criteria: patients who do not want to participate in the study or are admitted to the hospital during the study.

##### Intervention groups

In the control group, no intervention is performed and these patients receive training and treatment as usual. In the intervention group, one gastrolith capsule containing Shirazi thyme essential oil was given to the patients daily for 6 weeks after lunch and dinner.

#### Main outcome variables

Severity of gastroesophageal reflux

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240116060709N1**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

##### Registration date

2024-02-21, 1402/12/02

##### Registrant information

##### Name

Benyamin Borhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5582 3445

##### Email address

benyaminborhani72@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-24, 1402/12/05

##### Expected recruitment end date

2024-03-10, 1402/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of Shirazi thyme essential oil on the clinical symptoms of patients with gastroesophageal reflux disease

**Public title**

Investigating the effect of Shirazi thyme essential oil on the clinical symptoms of patients with gastroesophageal reflux

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to attend the study Patients with second grade reflux severity (patients who were not able to resolve their symptoms with lifestyle changes alone) Age 20 to 60 years Absence of pregnancy and breastfeeding Absence of allergy to thyme Not having diabetes No previous upper gastrointestinal surgery Absence of positive and clinically significant gastrointestinal bleeding in the last three months Absence of proven diseases such as: bleeding disorder, Barrett's Esophagus, esophageal varices, duodenal/stomach ulcer and upper gastrointestinal tract malignancy Able to read, understand and complete the questionnaire

**Exclusion criteria:**

Reluctance to continue research Hospitalization during the study Not using gastrolith capsules for more than 5 days

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After the pre-test, patients are randomly assigned to one of the intervention or control groups based on the random numbers table. For this purpose, a list of patients with entry criteria is prepared and no intervention is performed in the control group and gastrolith capsules are consumed twice a day in the intervention group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Gonabad University of Medical Sciences

**Street address**

Gonabad University of Medical Sciences, Ghadir Square

**City**

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**Province**

Razavi Khorasan

**Postal code**

9691793718

**Approval date**

2023-07-19, 1402/04/28

**Ethics committee reference number**

IR.GMU.REC.1402.073

**Health conditions studied****1****Description of health condition studied**

Gastroesophageal reflux disease

**ICD-10 code**

K21.9

**ICD-10 code description**

Gastro-esophageal reflux disease without esophagitis

**Primary outcomes****1****Description**

Percentage of people with second-degree gastroesophageal reflux (patients who were not able to resolve their symptoms only by lifestyle changes)

**Timepoint**

Before the intervention and 45 days after the intervention

**Method of measurement**

Reflux disease questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: After completing the demographic questionnaire and gastric reflux disease questionnaire,

one gastrolith capsule (containing 20 mg of Shirazi thyme essential oil, manufactured by Iran's Barij Essential Pharmaceutical Company) is given to the patients after noon and night meals for 6 weeks. After every 7 days, the use of Gastrolite capsules is stopped for 2 days, and after 2 days of non-use, the use of Gastrolite capsules is resumed. Drug consumption is controlled by telephone every week, after the end of the study, the patients will complete the reflux disease questionnaire again, and the patients who have not used Shirazi thyme essence capsules for 5 days will be excluded from the study.

**Category**

Treatment - Drugs

**2****Description**

Control group: After completing the demographic questionnaire and the gastric reflux disease questionnaire, no intervention is performed for the patients and for these patients the educational and treatment procedures are carried out normally.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Gonabad University of Medical Sciences

**Full name of responsible person**

Benyamin Borhani

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Leila Sadegh Moghadam

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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**

Gonabad 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**

Gonabad University of Medical Sciences

**Full name of responsible person**

Benyamin Borhani

**Position**

Senior students

**Latest degree**

A Level or less

**Other areas of specialty/work**

Others

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Gonabad University of Medical Sciences  
**Full name of responsible person**  
Habib Shareinia  
**Position**  
Associate professor  
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Ph.D.  
**Other areas of specialty/work**  
Others  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Gonabad University of Medical Sciences  
**Full name of responsible person**  
Benyamin Borhani  
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senior students  
**Latest degree**  
A Level or less  
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## 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

All potential data can be shared once individuals are identified.

### When the data will become available and for how long

The access period starts 6 months after the publication of the results

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Researchers working in academic and scientific institutions can apply for clinical use after coordination with the main researcher of this research.

### From where data/document is obtainable

Name: Benyamin Borhani Phone number: 00989155355135 email: Benyaminborhani72@gmail.com Postal code: 9674110033

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

After the request is announced by the requester, the request is reviewed and information is sent to the requester within one month.

### Comments