

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Evaluation of the efficacy and safety of stillen in comparison with pantoprazole in controlling the symptoms of gastro-myopic reflux in patients referred to the gastroenterology clinic of Baqiyatallah Hospital

#### Protocol summary

##### Study aim

Aim of this was evaluation of acetylene in comparison with oral pantoprazole in controlling gastro-esophageal reflux symptoms in patients referred to gastroenterology clinic of Baqiyatallah Hospital.

##### Design

This assessment was a phase 3 clinical trial and was conducted on patients with gastroesophageal reflux disease. At first, symptoms were recorded according to RSI questionnaire. If they scored more than 13, reflux disease was diagnosed. Patients divided into two groups of 30, and each group received pentaprazole 40 mg daily before breakfast, first group received acetylene before bedtime, and second group continued to take same treatment as Pantoprazole, duration of protocol was 6 weeks. Patients in 3 and 6 weeks were evaluated for clinical manifestations.

##### Settings and conduct

This study was carried out as a clinical trial at gastroenterology clinic of Erfan Hospital in Tehran, also study will also be single blinded and patients will be blinded in study.

##### Participants/Inclusion and exclusion criteria

Patients completing an consent more than 18 years of age, non-smokers and approved for diagnosis of reflux disease with clinical and paraclinical findings are considered as a study group. Also patient's should not be in life-threatening, not participate in another clinical trial at same time and should not be treated with interfering drugs before intervention, they are considered as a research group. Also, pregnant patients, psychiatric and veterans, due to pulmonary symptoms, with any severe complications in use of medications, exacerbation of signs during study and treatment discontinuation, will be excluded from study.

##### Intervention groups

Intervention group: In this group, pantoprazole is used 40

mg before breakfast and acetylene 60 mg before bedtime. Control group: In this group, pantoprazole is used 40 mg before breakfast.

##### Main outcome variables

Gastro-esophageal reflux

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180422039378N1**

Registration date: **2018-06-11, 1397/03/21**

Registration timing: **retrospective**

Last update: **2018-06-11, 1397/03/21**

Update count: **0**

##### Registration date

2018-06-11, 1397/03/21

##### Registrant information

##### Name

nasrollah shafighi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8126 0043

##### Email address

stu.shafighi63@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-19, 1396/01/30

##### Expected recruitment end date

2018-02-18, 1396/11/29

**Actual recruitment start date**

2017-04-20, 1396/01/31

**Actual recruitment end date**

2018-02-19, 1396/11/30

**Trial completion date**

empty

**Scientific title**

Evaluation of the efficacy and safety of stillen in comparison with pantoprazole in controlling the symptoms of gastro-myopic reflux in patients referred to the gastroenterology clinic of Baqiyatallah Hospital

**Public title**

Evaluation of the effect of acetylene drug in comparison with oral administration of pantoprazole in controlling symptoms of gastro-esophageal reflux.

**Purpose**

Treatment

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

Completion of informed consent form Diagnosis of reflux disease is confirmed by clinical and paraclinical findings. The patient's condition is not life-threatening. Do not participate in another clinical trial at the same time. Do not interact with medication before intervention. Like beta blocker inhibitors and herbal medicines or drugs that are harmful for treatment of reflux, such as theophylline, and others. Age over 18 years No smoking in the past Not pregnancy Failure to enter the plan for patients with psychiatric and veterinary injuries due to pulmonary symptoms

**Exclusion criteria:**

The occurrence of severe drug-related symptoms and severe hypersensitivity to drugs that can not be controlled. Signs and symptoms of the patient have worsened during the study. Those patients who have not consumed their medication for more than a week. History of chemical gas and severe pulmonary disease. Pregnant or intending to have a pregnancy Presence and observation of drug interactions

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomization we will use the block method, based on this two lists of patients are provided and each list is placed in one of the groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This means that patients in groups do not know the used drugs.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Baqiyatallah University of Medical Sciences

**Street address**

Vanak Square, Mulla Sadra St.

**City**

Tehran

**Province**

Tehran

**Postal code**

88191248

**Approval date**

2017-04-09, 1396/01/20

**Ethics committee reference number**

IR.BMSC.REC.1396.445

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

Gastro-esophageal reflux

**ICD-10 code**

K21

**ICD-10 code description**

Gastro-esophageal reflux disease

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

Symptoms of Gastro-esophageal reflux Disease

**Timepoint**

Before starting treatment, as well as at 3 and 6 weeks after starting treatment

**Method of measurement**

Interview with patients using reflux symptom index questionnaire

**Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: In this group, pantoprazole 40 mg before breakfast and acetylene 60 mg before bedtime, is used.

### Category

Treatment - Drugs

2

### Description

Control group: In this group, pantoprazole 40 mg before breakfast, is used.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Erfan Hospital

#### Full name of responsible person

Dr. Hossein Khedmat

#### Street address

Sheikh Bahay Street

#### City

Tehran

#### Province

Tehran

#### Postal code

88191248

#### Phone

+98 21 8126 4300

#### Email

dr.shafighi63@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Gholam Hossein Alishiri

#### Street address

Sheikh Bahay avenue

#### City

Tehran

#### Province

Tehran

#### Postal code

8819124812

#### Phone

+98 21 8126 4354

#### Email

dr.shafighi63@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Dr. Hossein Khammat

#### Position

professor of Gastroenterologist

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gastroenterologist

#### Street address

Sheikh Bahay avenue

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Tehran

#### Province

Tehran

#### Postal code

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Dr. Nasrallah Shafiqi

#### Position

Internal Specialist resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Internal Medicine

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8819124812  
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dr.shafighi63@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Dr. Hossein Khammat  
**Position**  
Gastroenterologist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Gastroenterologist  
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**Province**  
Tehran

**Postal code**  
8819124812  
**Phone**  
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**Email**  
dr.shafighi63@gmail.com

## 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