

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

To evaluate the efficacy and safety of Aloe vera capsule in gastroesophageal reflux disease patients and comparing the control of symptoms with pantoprazole

Protocol summary

Study aim

To evaluate the efficacy and safety of Aloe vera capsule in gastroesophageal reflux disease patients and comparing the control of symptoms with pantoprazole; and Achieving a beneficial, cheap, and less side effect drug.

Design

A clinical trial was conducted on 120 patients in three groups of control, treatment and placebo based on community and pragmatic, with parallel, blind, randomized, 40 person groups. We study pantoprazole 40 mg tablets once daily in all three groups. In addition, one group received Aloe vera 500 mg twice daily and the other with a similar Aloe vera capsule in place of placebo. The study period is 28 days.

Settings and conduct

Patients are required to use Aloe Vera capsule or Pantoprazole twice or once daily for 28 days and then answer the questionnaire .

Participants/Inclusion and exclusion criteria

Inclusion criteria: obtaining the informed consent of the patient; diagnosis of reflux has been confirmed by a physician Considering clinical and para clinical findings; the patient's condition is not life-threatening; don't participate in another clinical trial at the same time; have not been treated with any interactive medication before intervention; such as H2 blocker inhibitors and herbal medicines or drugs that are harmful to treatment for reflux such as theophylline and the like. Exclusion criteria: patients' age is less than 12 and more than 80 years old; the patient is pregnant.

Intervention groups

Aloe Vera capsule 500 mg twice daily and Pantoprazole 40 mg tablet once daily for 28 days in the treatment group, placebo capsule similar to Aloe Vera capsule and Pantoprazole 40 mg tablet once daily for 28 days in the treatment group, Pantoprazole for 28 days and Once a

day in control group for 28 days

Main outcome variables

Swelling; nausea and vomiting; heartburn; indigestion; shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N42**

Registration date: **2019-11-30, 1398/09/09**

Registration timing: **prospective**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

Registration date

2019-11-30, 1398/09/09

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the efficacy and safety of Aloe vera capsule in gastroesophageal reflux disease patients and comparing the control of symptoms with pantoprazole

Public title

Effect of Aloe vera capsule in control of gastroesophageal reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Obtaining the informed consent of the patient. Diagnosis of reflux has been confirmed by a physician Considering clinical and para clinical findings. The patient's condition is not life-threatening.

Exclusion criteria:

Have been treated with any interactive medication before intervention; such as H2 blocker inhibitors and herbal medicines or drugs that are harmful to treatment for reflux such as theophylline and the like. Participate in another clinical trial at the same time. Pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Accidental assignment to intervention and control groups using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient groups are divided into three groups, and every one including researcher, health care personnel (doctors, nurses, pharmacists), participating patients involved in the study are not known to have any type of control or intervention. All patients are aware of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee in Research of Faculty of Pharmacy and Pharmaceutical Sciences - Islamic Azad Unive

Street address

Islamic Azad University - Pharmaceutical Sciences Branch - yakhchal St. - Shariati Ave.

City

Tehran

Province

Tehran

Postal code

193956466

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.IAU.PS.REC.1398.174

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

gastroesophageal reflux disease

ICD-10 code

K20-K31

ICD-10 code description

Diseases of oesophagus, stomach and duodenum

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

Bloat

Timepoint

Before intervention, 2 and 4 weeks after intervention

Method of measurement

Questionnaire

2**Description**

Nausea and vomiting

Timepoint

Before intervention, 2 and 4 weeks after intervention

Method of measurement

Questionnaire

3**Description**

Heartburn

Timepoint

Before intervention, 2 and 4 weeks after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention, 2 and 4 weeks after intervention

Method of measurement

Heartburn/Reflux Symptoms Questionnaire

2

Description

Drug Adverse effects

Timepoint

After prescription of drug

Method of measurement

Data form

Intervention groups

1

Description

Intervention group: Aloe Vera capsule for 28 day, twice a day and pantoprazole for 28 day, once a day

Category

Treatment - Drugs

2

Description

Control group: pantoprazole for 28 day, once a day

Category

Treatment - Drugs

3

Description

Intervention group: placebo capsule for 28 days, twice daily and pantoprazole for 28 days, once daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiyyatollah University of Medical Sciences

Full name of responsible person

Yunes Panahi

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Mollasadra Ave

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Fax

Email

Yunespanahi@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabib daru pharmaceutical company

Full name of responsible person

Mahboube Mahoubi

Street address

Homa Building, Unit 3, Shahid Motahhari Boulevard,
Kashan, Alley

City

Isfahan

Province

Isfahan

Postal code

1435915371

Phone

+98 31 5557 1000

Email

Mahboubi1357@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabib daru pharmaceutical company

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yunes Panahi

Position

Clinical pharmacist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Islamic Azad University, Yakhchal St.

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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

Yunes Panahi

Position

Clinical pharmacist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Zahra Mortazavi

Position

Pharmacy student

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

clinical study report will be published in the form of an article

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Researchers in the field of health

Under which criteria data/document could be used

If the documentation remains protected

From where data/document is obtainable

Dr.Yunes panahi yunespanahi@bmsu.ac.ir

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

Send an email to the project manager

Comments