Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

To evaluate the efficacy and safty 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 pentoprazole 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; dont 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 the 12 and more than 80 years old; the patient is pregnant.

Intervention groups
Aloe Vera capsule 500 mg twice daily and Pentoprazole 40 mg tablet once daily for 28 days in the treatment group, placebo capsule similar to Aloe Vera capsule and Pentoprazole 40 mg tablet once daily for 28 days in the treatment group, Pentoprazole 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 safty 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 pentoprazole 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

Street address

Mollasadra Ave

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8248 2503

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

Isfehan

Province

Isfehan

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
Street address
Mollasadra Ave
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8248 2503
Email
Yunespanahi@bmsu.ac.ir

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
Medical Pharmacy
Street address
Mollasadra Ave
City
tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 2503
Email
Yunespanahi@bmsu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zahra Mortazavi
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Islamic Azad University, Yakhchal St.
City
Tehran
Province
Tehran
Postal code
194193311
Phone
+98 21 2264 0051
Email
zahramortazavi@yahoo.com

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