Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the Effect of extracts of Cydonia oblonga, Punica granatum and Phyllanthus emblica on the prevention of gastric and peptic ulcer disease in hospitalized burned patients at Ayatollah Taleghani hospital in Ahvaz: double blind clinical trial

Protocol summary

Study aim

Evaluation of the effect of syrup, including Quince, pomegranate and Phyllanthus emblica in the prevention of gastroesophageal reflux disease and peptic ulcer in hospitalized burned patients at Ayatollah Taleghani Hospital in Ahvaz

Design

Clinical trial of phase 2-3 with control and intervention groups, with parallel groups, double blind, randomized

Settings and conduct

This study will be performed by clinical trial on patients over 18 years of age with a burn rate of 35% and above who refer to Taleghani Hospital in Ahvaz. Patients will receive daily treatment (pentoprazole 80 mg daily). These patients are randomly will be divided into two groups, who accidentally will receive a bottle containing the drug or herbal syrup. The unique code provided by the software will be used on pharmaceutical boxes. Symptoms related to gastroesophageal reflux disease will be measured before and after the intervention using the questionnaire. This questionnaire has thirteen questions. These cases are scored between 0 and 4 by the subjects. Higher scores on reflux are more severe.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age with a burn rate of 35% or more who are hospitalized for more than ten days. The women in the study had a negative pregnancy test No history of asthma and heart disease Exclusion criteria: Patients with a history of endoscopic confirmed peptic ulcer. Gasteric cancer, Allergy to plants especially fruits of Quince, Phyllanthus emblica and pomegranate flowers

Intervention groups

Patients are randomly will be divided into two groups. In addition to receiving pentoprazole daily, the test and control groups will receive 30 ml of herbal syrup or placebo twice a day for a week.

Main outcome variables

Heartburn; Feeling bloated; Early satiety; Belching; Feeling of heaviness in the stomach after eating; Feeling a bitter liquid in the throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200128046288N2**
Registration date: **2020-05-16, 1399/02/27**
Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**
Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Fereshteh Golfakhrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8378

Email address

golfakhrabadi-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-03, 1399/03/14

Expected recruitment end date
2020-11-19, 1399/08/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the Effect of extracts of Cydonia oblonga, Punica granatum and Phyllanthus emblica on the prevention of gastric and peptic ulcer disease in hospitalized burned patients at Ayatollah Taleghani hospital in Ahvaz: double blind clinical trial

Public title
Evaluation the effect of extracts of Cydonia oblonga, Punica granatum and Phyllanthus emblica on the prevention of gastric disease in hospitalized burned patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age with a burn rate of 35% or more who are hospitalized for more than ten days. The women in the study had a negative pregnancy test No history of asthma and heart disease (heart block and heart failure)
Exclusion criteria:
Patients with a history of endoscopic confirmed peptic ulcer. Gasteric cancer Allergy to plants especially fruits of Quince, Phyllanthus emblica and pomegranate flowers
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method is used Blocking is used to balance the number of samples assigned to each study group, because we have two intervention groups, use equal 4 blocks and create all 4 possible modes and then with Excel software we randomly select a number of blocks. The label of interventions to one of the letters A or B and the sequence of randomization determined by the statistical consultant. For allocation concealment, drug delivery and the sequence of randomization is not available to researchers and evaluators while is the responsibility of the off-site individual.
Blinding (investigator's opinion)
Double blinded
Blinding description
Unique codes, which is generated by the software, will be used on the drug and placebo boxes. By entering each individual into the study based on the produced sequence, the drug or placebo box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences,
Street address
Ahvaz Jundishapur University of Medical Sciences,, Golestan street
City
Ahvaz
Province
Khouzestan
Postal code
-61357-15794
Approval date
2020-04-24, 1399/02/05
Ethics committee reference number
IR.AJUMS.REC.1399.097

Health conditions studied

1

Description of health condition studied
Gastric reflux and peptic ulcer
ICD-10 code
K27
ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
Heartburn
Timepoint

Before and a week after the intervention
Method of measurement
questionnaire

2

Description
Bloating
Timepoint
Before and a week after the intervention
Method of measurement
Gastric reflux questionnaire

3

Description
Feeling of heaviness in the stomach after eating
Timepoint
Before and a week after the intervention
Method of measurement
Gastric reflux questionnaire

4

Description
Early satiety
Timepoint
Before and a week after the intervention
Method of measurement
Gastric reflux questionnaire

5

Description
Feeling a bitter liquid (acid) in the throat
Timepoint
Before and a week after the intervention
Method of measurement
Gastric reflux questionnaire

6

Description
Belching
Timepoint
Before and a week after the intervention
Method of measurement
Gastric reflux questionnaire

Secondary outcomes

1

Description
The rate of drug side effects
Timepoint
During drug use
Method of measurement
Patient Report

Intervention groups

1

Description
Intervention group: In addition to receiving pentoprazole, 30 ml of herbal syrup will be taken twice a day for a week. The herbal syrup includes fruit of Quince, Phyllanthus emblica and pomegranate flowers, which will be made by the researchers of the project and based on the formula of Iranian traditional medicine resources, which will be standardized based on pectin, tannins and phenolic content.
Category
Prevention

2

Description
Control group: In addition to pentoprazole, they will receive 30 ml of placebo twice a day for a week.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani hospital in Ahvaz:
Full name of responsible person
Abdolreza Sheikhi
Street address
In front of police station 23, Phase 2 of Padadshahr, Ahvaz
City
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6187954386
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golfakhrabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street
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Province
Khouzestan
Postal code

6135733184
Phone
+98 61 3336 2414
Email
Badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Fereshteh golfakhrabadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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golfakhrabadi@yahoo.com

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
Only part of the data will be shared

When the data will become available and for how long

The access time is up to 6 months after the results are published

To whom data/document is available

Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.

Under which criteria data/document could be used

Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.

From where data/document is obtainable

Applicants can email the responsible author to receive the requested data golfakhrabadi@yahoo.com

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

Applicants will have access to the data from the present study by emailing the responsible author for up to one month.

Comments