Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 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)

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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

Ahvaz

Province

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Postal code

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Phone

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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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6135733184

Phone

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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

Contact

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Full name of responsible person

Fereshteh golfakhrabadi

Position

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Person responsible for updating data

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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

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