Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of herbal supplement capsule on treatment of peptic disease patients

Protocol summary

Study aim

Evaluation of the effect of Perforate St John's-wort , Matricaria chamomilla , Citrus aurantium , Portulaca oleracea in patients with gastric ulcers.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized

Settings and conduct

Endoscopic gastric ulceration is confirmed in both groups. Patients in group 1 were asked to take a herbal capsule one hour before each meal with their standard drug. Patients are asked to continue their usual diet during the study. Patients will be visited at the end of the eighth week and re-examined by endoscopy in addition to a clinical examination. This study is double blind and will be done in hospitals of Islamic Azad universty,mashhad branch.

Participants/Inclusion and exclusion criteria

Gastric ulcer, willingness to participate in the study/ taking antidepressants agents (SSRI) , pregnancy, breastfeeding,history of alchohol consumption

Intervention groups

The intervention group consist of people who, receive the 600 mg herbal capsules which is made by pharmacist, one hour before each meal in addition to their standard medication for eight weeks. These capsules contain 150 mg of Perforate St John's-wort, 150 mg of Matricaria chamomilla , 150 mg of Citrus aurantium and 150 mg of Portulaca oleracea. Patients will be re-examined at the end of the 8th week by clinical and endoscopic examination. The control group also includes patients receiving starch capsules (placebo), in addition to their standard medication.

Main outcome variables

Gastric ulcer size on endoscopy. Epigastric pain and burning on clinical examination and visual analog scale (VAS)

General information

Reason for update

making a minor change in the title,so that it can show a more specific concept of the research

Acronym

IRCT registration information

IRCT registration number: **IRCT20151230025772N10**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**
Update count: **1**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Seyyed Abbas Zojaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2717

Email address

zojajia881@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the effect of herbal supplement capsule on treatment of peptic disease patients

Public title
Evaluating the effect of herbal supplement capsule on treatment of peptic disease patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gastric ulcer or erosion, confirmed by endoscopy
Exclusion criteria:
Taking antidepressants agents (SSRI) History of alcohol consumption Breastfeeding and pregnancy
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization. Sealed envelopes are used to hide the treatment. Random numbers between 0 and 1 will be generated using the calculator. Envelopes that receive codes between 0 and 0.5 will be filled with placebo and envelopes that receive codes between 0.5 and 1 will be filled with medicine. In this way, the envelopes are arranged in a random order. The envelopes are thick and opaque. Patients and physicians do not know the content of the codes until the end of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, sealed envelopes are used to hide the treatment from the physician and patients. Physician and patients are unaware of the contents of the drug or placebo envelopes. Herbal medicines and placebo are being placed inside similar capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University-Mashhad Branch
Street address
Shahinfar Medical School, Emam Khomeini Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9187147578
Approval date
2022-08-29, 1401/06/07
Ethics committee reference number
IR.IAU.MSHD.REC.1401.086

Health conditions studied

1

Description of health condition studied
Gastric ulcer
ICD-10 code
K25
ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
Gastric ulcer size
Timepoint
before intervention/8 weeks after intervention
Method of measurement
endoscopy

2

Description
Epigastic discomfort
Timepoint
before intervention/8 weeks after intervention
Method of measurement
Visual Analogue Scale

3

Description
Helicobactepylori infection
Timepoint
before intervention/8 weeks after intervention
Method of measurement
endoscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients receive herbal capsules which are made by pharmacist, up to 8 weeks along with their standard medication one hour before each meal. The weight of each capsule will be 600 mg and its contents will include 150 mg of Perforate St John's-wort, 150 mg of Portulaca oleracea, 150 g of Matricaria chamomilla and 150 mg of Citrus aurantium
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
22th Bahman Hospital
Full name of responsible person
Dr. Elham Mokhtari Amir majdi
Street address
39th baba nazar-Baba Nazar highway
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9174675155
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emokhtaria@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zojaj Darman Toos pharmaceutical company
Full name of responsible person
Seyyed Abbas Zojaji
Street address
Pharmaceutical Technology development center of Mashhad university of medical science, Buali square.
City
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Postal code
9196773113
Phone
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Email
info@zojaj.club
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zojaj Darman Toos pharmaceutical company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Zojaj Darman Toos Pharmaceutical Company
Full name of responsible person
Seyyed Abbas Zojaji
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Elham Mokhtari Amir Majdi
Position
Assitant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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
It is not yet known if there will be a plan to make this available
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available