Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effect of Zed-rest capsules on treatment of gastric and duodenal ulcers

Protocol summary

Study aim
Evaluation of the effect of chamomile, tea, spring orange and purslane on Z-Rest in Patients with gastric and duodenal 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 Zed-rest 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 a double blind study at 550 Army Hospital of Mashhad.

Participants/Inclusion and exclusion criteria
Inclusion criteria: : gastric and duodenal ulcer, willingness to participate in study, no history of alcohol use Exclusion criteria: : special or chronic illnesses, other liver disorders, use of selective serotonin reuptake inhibitor(SSRI) antidepressants, pregnancy, lactation.

Intervention groups
The intervention group consist of people who, receive the Zed-rest 600 mg capsules from Zojaj Darman Tous company, one hour before each meal in addition to their standard medication for eight weeks. These capsules contain 150 mg of hypericum, 150 mg of purslane eggs, 150 g of chamomile and 150 mg of orange blossom. Patients are re-examined at the end of the eight week by clinical and endoscopic examination. The control group also includes patients receiving starch capsules (placebo) from Zojaj Darman Tous company, in addition to their standard medication.

Main outcome variables
Gastric and duodenal ulcer size on endoscopy. Epigastric pain and burning on clinical examination and visual analog scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151230025772N8**
Registration date: **2020-05-24, 1399/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-24, 1399/03/04**
Update count: **0**

Registration date
2020-05-24, 1399/03/04

Registrant information

Name
Seyyed Abbas Zojaji

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3711 2717

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zojajia881@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-18, 1398/11/29

Expected recruitment end date
2020-06-18, 1399/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the effect of Zed-rest capsules on treatment of gastric and duodenal ulcers

Public title
Evaluating the effect of Zed-rest capsules on gastric and duodenal ulcers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
gastric and duodenal ulcer willingness to participate in study no history of alcohol use
Exclusion criteria:
special or chronic illnesses, such as immune disease, hypothyroidism, lupus, kidney failure and cancer other liver disorders such as cirrhosis and hepatitis B using selective serotonin reuptake inhibitor (SSRI) antidepressants Pregnancy lactation
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization. Sealed envelopes were used to hide the treatment. Random numbers between 0 and 1 were generated using the calculator. Envelopes that received codes between 0 and 0.5 were filled with placebo and envelopes that received codes between 0.5 and 1 were filled with medicine. In this way, the envelopes were arranged in a random order. The envelopes were thick and opaque. Patients and physicians did 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 were used to hide the treatment from the physician and patients. Physician and patients were unaware of the contents of the drug or placebo envelopes. Herbal medicines and placebo were 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
2019-06-25, 1398/04/04
Ethics committee reference number
IR.IAU.MSHD.REC.1398.062

Health conditions studied

1

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

2

Description of health condition studied
Duodenal ulcer
ICD-10 code
K26
ICD-10 code description
Duodenal ulcer

Primary outcomes

1

Description
gastric and duodenal ulcers size
Timepoint
before intervention, 8 weeks after intervention
Method of measurement
endoscopy

2

Description
heart burn and epigastric pain
Timepoint
before intervention, 8 weeks after intervention
Method of measurement
Physical examination, Visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients receive Z-rest capsules which are the product of Zojaj Darman Tous company, 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 tea, 150 mg of purslane eggs, 150 g of chamomile and 150 mg of spring orange leaf.
Category
Treatment - Drugs

2

Description
Control group: patients receive starch capsules (placebo) which are the product of Zojaj Darman Tous company, one hour before each meal in addition to their standard treatment up to 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Army 550 Hospital
Full name of responsible person
Seyed Abbas Zojaji
Street address
Army 550 Hospital, Beheshti Ave, Bahar Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mohammad Reza Khakzad Oryani
Street address
Innovative medical research center, Shahinfar university of medical sciences, Imam Khomeini Ave.
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+98 51 3853 6008
Email
IMRC@mshdiau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
10
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

2

Sponsor
Name of organization / entity
The Zojaj Darman Toos Pharmaceutical Company
Full name of responsible person
Seyed Abbas Zojaji
Street address
Pharmaceutical Technology Incubator of Mashhad university of medical science, Buali square.
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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
The Zojaj Darman Toos Pharmaceutical Company
Proportion provided by this source
90
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyyed Abbas Zojaji
Position
Non-faculty pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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