

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 alcohol 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**

Epigastric discomfort

**Timepoint**

before intervention/8 weeks after intervention

**Method of measurement**

Visual Analogue Scale

**3****Description**

Helicobacter pylori 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

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9174675155

#### Phone

+98 51 3259 5517

#### Email

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

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9196773113

#### Phone

+98 51 3711 2611

#### 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

#### Street address

PharmaceutDevelopment center of Mashhad university of medical science, Buali square.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9196773113

#### Phone

+98 51 3711 2611

#### Email

info@zojaj.club

## 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

#### Street address

Shahinfar Medical School, Emam Khomeini Ave.

#### City

Mashhad

#### Province

Razavi Khorasan  
**Postal code**  
9187147578  
**Phone**  
+98 51 3225 0041  
**Email**  
emokhtaria@gmail.com

Razavi Khorasan  
**Postal code**  
9196773113  
**Phone**  
+98 51 3711 2611  
**Email**  
info@zozaj.club

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zozaj Darman Toos Pharmaceutical Company  
**Full name of responsible person**  
Seyyed Abbas Zozaji  
**Position**  
professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Pharmaceutical Technology development center of  
Mashhad university of medical science, Buali square  
**City**  
Mashhad  
**Province**

## 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