# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Comparison of the Effectiveness of Omeprazole with herbal drug that is composed of essential oil of Zataria multiflora Boiss, Trachyspermum ammi and Anethum graveolens L, in treatment of Gastro-esophageal reflux disease (GERD).

## Protocol summary

**Study aim**

Study the influence of a herbal drug that is composed of essential oil of Zataria multiflora Boiss, Trachyspermum ammi and Anethum graveolens L, in treatment of Gastro-esophageal reflux disease.

**Design**

Study population is the patients that referred to gastroenterology clinic and sample size for study is 60 person. patients are divided into two control and intervention groups by simple randomization and using the Random Allocation software.

**Settings and conduct**

This is a randomized, double-blind clinical trial that is done in gastrointestinal clinic of Shahid Mohammadi Hospial in Bandar Abbas city. In this study, blind persons are participants, clinical caregiver and responsible individual for evaluating the outcome of treatment.

**Participants/Inclusion and exclusion criteria**

The inclusion criteria are written consent, complete knowledge about the study and being diagnosed with Gastro-esophageal reflux disease based on the Montreal criteria. The exclusion criteria are lack of consent to continue their participation, kidney or liver diseases, warning symptoms of gastric and intestinal cancers, other chronic gastrointestinal diseases and peptic ulcer disease.

**Intervention groups**

The study will last for 14 days, the patients of intervention group are received 2 capsules daily containing the essential oil of the plant, and the control group are received one Omeprazole 20 mg capsule daily.

**Main outcome variables**

Patient characteristics such as severity of disease symptoms, and quality of life will enter into a form at the beginning, at the end, and two weeks after completion of treatment. After completion of the treatment, the safety of the treatment regimen is assessed by laboratory tests and through recording adverse drug reactions.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016072129026N1**
Registration date: **2016-12-07, 1395/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-02, 1396/10/12**
Update count: **1**

**Registration date**

2016-12-07, 1395/09/17

**Registrant information**

**Name**
Ghasem Bordbar
**Name of organization / entity**
Hormozgan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 76 3333 3280
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ghasem.bordbar@hums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Hormozgan University of Medical Science.Hormozgan Science & Technology Park.

**Expected recruitment start date**

2016-08-05, 1395/05/15

**Expected recruitment end date**
2017-09-01, 1396/06/10
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the Effectiveness of Omeprazole with herbal drug that is composed of essential oil of Zataria multiflora Boiss, Trachyspermum ammi and Anethum graveolens L, in treatment of Gastro-esophageal reflux disease (GERD).

**Public title**
Herbal drug for treatment of Gastro-esophageal reflux disease
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Written consent and complete knowledge about the study; being diagnosed with Gastro-esophageal reflux disease based on the Montreal definition.
**Exclusion criteria:**
The participants' lack of consent to continue their participation in the study; kidney and liver diseases based on laboratory tests; warning symptoms of gastric and esophageal cancers, other chronic digestive diseases and peptic ulcer disease based on patient history, physical examination, laboratory tests and, if necessary, upper endoscopy.
**Age**
From **15 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
simple randomization method and using the Random Allocation software.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
After the patient is visited and proved by gastroenterologist to have required conditions ,the informed consent is obtained from the patients and they will be referred to GP to receive the drug. By simple randomization method and using the random Allocation, GP puts the patients in two equal group of control and interference.The patients in the control group receive medicinal regimen of type A and the patients in the interference group receive the medicinal regimen of type B. The drugs are placed in the containers with the same shape and appearance with code of A and B on them by the way the patients are uninformed about the regimen type. Finally the assessment is done by a third individual (a trained medical student) that is uninformed about the type of regimen A and B .
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Hormozgan University of Medical Sciences
**Street address**
Vice-chancellery for research, Shahid Mohamadi hospital, Bandar Abbas, Iran.
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7915915517
**Approval date**
2015-07-07, 1394/04/16
**Ethics committee reference number**
HUMS.REC.1394.012

## Health conditions studied

### 1

**Description of health condition studied**
Gastro-oesophageal reflux disease
**ICD-10 code**
K21
**ICD-10 code description**
Gastro-oesophageal reflux disease

## Primary outcomes

### 1

**Description**
average score of persons in (Gastrointestinal SymptomRating Scale (GSRS
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**

Gastrointestinal SymptomRating Scale (GSRS)

**2**

**Description**
average score of persons in GSRS indigestion score.
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**
Gastrointestinal SymptomRating Scale (GSRS)

**3**

**Description**
average score of persons in GSRS abdominal pain.
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**
Gastrointestinal SymptomRating Scale (GSRS)

**4**

**Description**
average score of persons in GSRS Reflux score.
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**
Gastrointestinal SymptomRating Scale (GSRS)

**5**

**Description**
Quality of life
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**
SF-36 Healthy Survey questionnaire

**6**

**Description**
Epigastric pain syndrome(EPS)
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**
VAS Score(0-10)

**7**

**Description**
postprandial distress syndrom(PDS)
**Timepoint**
Before intervention, end of intervention, 2 weeks after intervention
**Method of measurement**
VAS Score(0-10)

## Secondary outcomes

**1**

**Description**
Amount of drug consumption
**Timepoint**
after intervention
**Method of measurement**
By checking the residual amount of drug after intervention

**2**

**Description**
Elevation of liver enzymes
**Timepoint**
Before and after intervention
**Method of measurement**
labratory test(AST,ALT,ALP,Billi T,D)

**3**

**Description**
Dysfunction of kidney
**Timepoint**
Before and after intervention
**Method of measurement**
labratory tests(Bun ,Cr)

**4**

**Description**
drug side effects
**Timepoint**
During and after intervention
**Method of measurement**
Entry the side effects by patient andclinical caregiver in side effects form

## Intervention groups

**1**

**Description**
Intervention group: Prescription of edible capsule containing 180mg of essential oil of Ajwain fruit, Zataria Multifora and Dill oil, 2 times a day for 2 weeks.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Prescription of omeprazole 20 mg capsule once a day for 2 weeks
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Shahid Mohamadi hospital

**Full name of responsible person**
Ghasem Bordbar

**Street address**
Shahid Mohamadi hospital, Bandar abbas, Hormozgan, Iran

**City**
Bandar abbas

**Province**
Hormozgan

**Postal code**
7915915517

**Phone**
+98 76 3333 7192

**Email**
research@hums.ac.ir

**Web page address**
http://www.resv.hums.ac.ir/

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Hormozgan Science & Technology Park

**Full name of responsible person**
Majid Sarnay zade

**Street address**
Health Technology Incubation Center, Azadegan, Bandar Abbas, Iran.

**City**
Bandar Abbas

**Province**
Hormozgan

**Postal code**
۷۹۱۴۹۵۴۵۶۱

**Phone**
+98 76 3333 4016

**Email**
incubator.hmstp@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Hormozgan Science & Technology Park

**Proportion provided by this source**
80

**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**
Other

**2**

**Sponsor**

**Name of organization / entity**
Vice Chancellor for research of Hormozgan University of Medical Sciences

**Full name of responsible person**
Majid Sarnay zade

**Street address**
Vice Chancellor for research of Hormozgan University of Medical Sciences, Shahid Mohamadi hospital,Bandar Abbas, Iran

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**Email**
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**Web page address**
http://www.resv.hums.ac.ir/

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Vice Chancellor for research of Hormozgan University of Medical Sciences

**Proportion provided by this source**
20

**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**
Student research comitte, Vice-chancellery for research, Hormozgan University of Medical Siences.

**Full name of responsible person**
Ghasem Bordbar

**Position**
Medical student

**Latest degree**
Medical doctor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Latest degree**
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**Other areas of specialty/work**
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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**
According to the subject of the study, which is about an invention. To prevent misuse of the details of the study information, there is currently no way to publish information.
**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