

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 Hospital 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

Email address

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 Symptom Rating Scale (GSRS

Timepoint

Before intervention, end of intervention, 2 weeks after intervention

Method of measurement

Gastrointestinal Symptom Rating 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 Symptom Rating 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 Symptom Rating 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 Symptom Rating 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

laboratory test(AST,ALT,ALP,Billi T,D)

3

Description

Dysfunction of kidney

Timepoint

Before and after intervention

Method of measurement

laboratory tests(Bun ,Cr)

4

Description

drug side effects

Timepoint

During and after intervention

Method of measurement

Entry the side effects by patient and clinical 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

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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.

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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

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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

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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**Street address**

Student research comitte, Vice-chancellery for
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

medical student

Latest degree

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Web page address**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