

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Efficacy of herbal drug that is composed of essential oil of Zataria Multiflora Boiss, Trachyspermum Ammi and Anethum Graveolens L, in treatment of Functional dyspepsia (FD) and eradication of Helicobacter pylori(H.pylori) infection.

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 Functional dyspepsia and eradication of H.pylori infection.

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; being diagnosed with functional dyspepsia based on the ROME III criteria and presence of H.pylori infection using Stool Ag test. The exclusion criteria are lack of consent to continue their participation, kidney or liver diseases, warning symptoms of gastric and esophageal cancers, other chronic gastrointestinal diseases and peptic ulcer disease.

Intervention groups

The patients of intervention group will be received 3 capsules daily containing the essential oil of the plant for 20 days, and the control group will be received standard treatment Regime for 4 weeks.

Main outcome variables

patients of two groups two weeks after the end of treatment will be compared from the point of eradication of H.pylori infection. 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. 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: **IRCT20160721029026N4**

Registration date: **2017-12-31, 1396/10/10**

Registration timing: **retrospective**

Last update: **2017-12-31, 1396/10/10**

Update count: **0**

Registration date

2017-12-31, 1396/10/10

Registrant information

Name

Ghasem Bordbar

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hormozgan Science & Technology Park. Hormozgan University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of herbal drug that is composed of essential oil of Zataria Multiflora Boiss, Trachyspermum Ammi and Anethum Graveolens L, in treatment of Functional dyspepsia (FD) and eradication of Helicobacter pylori(H.pylori) infection.

Public title

Herbal Drug for Treatment of Functional Dyspepsia and eradication of Helicobacter pylori(H.pylori) infection.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Written consent and complete knowledge about the study; being diagnosed with Functional dyspepsia based on the ROME III criteria; The presence of H.pylori infection based on Stool antigen test.

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.

AgeFrom **15 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget 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, General Practitioner 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**

Vice-chancellery for research of Hormozgan University of Medical Science

Street address

Vice-chancellery for research, Shahid Mohamadi hospital, Bandar Abbas, Iran.

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Bandar Abbas

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7915915517

Approval date

2015-07-07, 1394/04/16

Ethics committee reference number

IR.HUMS.REC.1394.012

Health conditions studied**1****Description of health condition studied**

Functional Dyspepsia

ICD-10 code

K30

ICD-10 code description

Dyspepsia

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 abdominal pain.

Timepoint

Before intervention, end of intervention, 2 weeks after intervention

Method of measurement

Gastrointestinal Symptom Rating Scale (GSRS)

3

Description

Epigastric pain syndrome(EPS)

Timepoint

Before intervention, end of intervention, 2 weeks after intervention

Method of measurement

VAS Score(0-10)

4

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)

5

Description

postprandial distress syndrom

Timepoint

Before intervention, end of intervention, 2 weeks after intervention

Method of measurement

VAS Score(0-10)

6

Description

Quality of life

Timepoint

Before intervention, end of intervention, 2 weeks after intervention

Method of measurement

SF-36 Healthy Survey questionnaire

7

Description

Eradication oh H.pylori infection.

Timepoint

Before intervention, 2 weeks after intervention

Method of measurement

Stool Ag test

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 an after intervention

Method of measurement

Entry the side effects by patient and Responsible for study in side effects form

Intervention groups

1

Description

Intervention group: Prescription of edible capsule containing 180mg of essential oil of Ajwain fruit,zataria multifora,dill oil , 3 times a day for 20 days.

Category

Treatment - Drugs

2

Description

Control group: Prescription of Clarithromycin 500mg twice a day for 2 weeks, Amoxicillin 1gr twice a day for 2 weeks and Omeprazole 20 mg capsule once a day for 4 weeks.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohamadi hospital

Full name of responsible person

Ghasem Bordbar

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Shahid Mohamadi hospital, Bandar abbas,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan Science & Technology Park

Full name of responsible person

Majid Sarnay Zade

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Health Technology Incubation Center, Azadegan,
Bandar Abbas, Iran
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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

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

Hormozgan University of Medical Sciences

Full name of responsible person

Majid Sarnay Zade

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Vice Chancellor for research of Hormozgan University
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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

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 Doctor/ Researcher

Latest degree

Medical doctor

Other areas of specialty/work
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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