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 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; 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.
Age
From **15 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

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, 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.
City
Bandar Abbas
Province
Hormozgan
Postal code
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

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

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 of Medical Sciences, Shahid Mohamadi hospital, Bandar Abbas, Iran

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research@hums.ac.ir

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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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Person responsible for scientific inquiries

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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