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 Functional dyspepsia (FD).

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.

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 functional dyspepsia based on the ROME III criteria. 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 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: **IRCT2016072629026N2**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-15, 1396/10/25**
Update count: **1**

Registration date
2016-11-27, 1395/09/07

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 Sciences, 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 Functional dyspepsia (FD).

Public title

Herbal Drug for Treatment of Functional Dyspepsia.

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.

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

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 GSRS abdominal pain.

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 (Gastrointestinal SymptomRating Scale (GSRS
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 indigestion score.
Timepoint
Before intervention, end of intervention, 2 weeks after intervention
Method of measurement
Gastrointestinal Symptom Rating Scale (GSRS)

4

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

5

Description
Postprandial distress syndrom(PDS)
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

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 and clinical caregiver in side effects form

Intervention groups

1

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

2

Description
ntervention 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

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
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
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/
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-chancellor 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 research, Shahid Mohamadi hospital, Bandar Abbas, Iran.
City
Bandar Abbas
Province
Hormozgan
Postal code
7915915517
Phone
+98 76 3333 7192
Fax
+98 76 3333 7192
Email
ghasem.bordbar@hums.ac.ir
Web page address

Person responsible for scientific 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 research, Shahid Mohamadi hospital, Bandar Abbas, Iran.

City
Bandar Abbas

Province
Hormozgan

Postal code
7915915517

Phone
+98 76 3333 7192

Fax
+98 76 3333 7192

Email
ghasem.bordbar@hums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Student research comitte, Vice-chancellery for research, Hormozgan university of Medical Science.

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 research, Shahid Mohamadi hospital, Bandar Abbas, Iran.

City
Bandar Abbas

Province
Hormozgan

Postal code
7915915517

Phone
+98 76 3333 7192

Fax
+98 76 3333 7192

Email
ghasem.bordbar@hums.ac.ir

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