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 Irritable bowel syndrome (IBS).

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 irritable bowel syndrome.

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 Irritable bowel syndrome based on the ROME III criteria. The exclusion criteria are the lack of consent to continue their participation, kidney or liver diseases, warning symptoms of gastrointestinal cancers, other chronic gastrointestinal diseases and peptic ulcer disease based on patient history, physical examination and medical records.

Intervention groups

The study will last for 14 days, the patients of intervention group are received capsules containing the essential oil of the plant twice times a day, and the control group are received Hyoscine tablet three times a day.

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 will also be assessed by laboratory tests and through recording adverse drug reactions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072629026N3**
Registration date: **2016-12-29, 1395/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-06, 1396/11/17**
Update count: **1**

Registration date

2016-12-29, 1395/10/09

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

2016-07-05, 1395/04/15

Expected recruitment end date
2017-09-16, 1396/06/25
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 Irritable bowel syndrome (IBS).

Public title
Herbal drug for treatment of Irritable bowel syndrome (IBS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Written consent and complete knowledge about the study. Being diagnosed with Irritable bowel syndrome 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 intestinal cancers, other chronic digestive diseases and peptic ulcer disease based on patient history, physical examination and medical records.
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 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
HUMS.REC.1394.012

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Quality of life
Timepoint
Before intervention, end of intervention and 2 weeks after intervention
Method of measurement
IBS Quality of life(IBS-QOL)

2

Description
Relife of symptoms
Timepoint
End of intervention and 2 weeks after intervention
Method of measurement
IBS Adequate relief (IBS-AR)

3

Description
Relife of symptoms
Timepoint
End of intervention and 2 weeks after intervention
Method of measurement
IBS Global Assessment improvement(IBS-GAI)

4

Description
Average score of IBS Symptom Severity Scale(IBS-SSS)
Timepoint
Before intervention, end of intervention and 2 weeks after intervention
Method of measurement
IBS Symptom Severity Scale(IBS-SSS)

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
Liver enzymes disorder
Timepoint
Before and after intervention
Method of measurement
Labratory test(AST,ALT,ALP,Billi T,D)

3

Description
Renal dysfunction
Timepoint
Before and after intervention
Method of measurement
Labratory test(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
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

2

Description
Control group: Prescription of hyoscine 10 mg tablet three 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

۷۹۱۴۹۵۴۵۴۱

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

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, 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

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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