

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 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 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

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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.

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Bandar Abbas

Province

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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

Relief of symptoms

Timepoint

End of intervention and 2 weeks after intervention

Method of measurement

IBS Adequate relief (IBS-AR)

3

Description

Relief 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

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

3

Description

Renal dysfunction

Timepoint

Before and after intervention

Method of measurement

Laboratory 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

Intervention group: Prescription of edible capsule containing 180mg of essential oil of Ajwain fruit, Zataria Multiflora 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

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Shahid Mohamadi hospital, Bandar Abbas, Hormozgan, Iran

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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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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
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Majid Sarnay zade
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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

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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