Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of a mixture of plant extracts and placebo on the severity of symptoms in patients with irritable bowel syndrom: A randomized double blind clinical trial

Protocol summary

Study aim
Evaluation of the clinical effect of Echinophora platyloba, Trachyspermum copticum and Zataria multiflora combination extracts on irritable bowel syndrome

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients

Settings and conduct
Study place: Gastroenterology Department of Bouali Hospital in Tehran. Type of blinding: Double blind. How to do blinding: To hide the diagnosis of the type of drug or placebo, we try to use the simulation of syrup forms (similar in taste and color) for drugs and placebo and install codes extracted from the table of random blocks on them and to keep participating patients, clinical researcher, health personnel (Nurses, etc.) who are responsible for caring for patients, data collectors and those evaluating outcomes completely blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People in the age range of 18 to 65 years; Having written consent; People who have a definite diagnosis of IBS based on the Rome Criteria. Non-inclusion criteria: Any concomitant disease other than IBS; People who are allergic to thyme or thyme or aloe vera or other herbal medicines; people who have a history of taking herbal medicines during the last 3 months; pregnant and lactating woman

Intervention groups
Intervention group: Syrup containing Echinophora platyloba, Trachyspermum copticum and Zataria multiflora combination extracts in combination with routine medications for irritable bowel syndrome. Control group: placebo syrup without mixed extracts in combination with routine medications for irritable bowel syndrome

Main outcome variables
IBS severity score; severity of abdominal pain; severity of bloating

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210404050833N1**
Registration date: **2021-07-21, 1400/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-21, 1400/04/30**
Update count: **0**

Registration date
2021-07-21, 1400/04/30

Registrant information

Name
Zeinab sadat Tabaee Fazli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2255 6336

Email address
zeinabfazli96@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-16, 1400/04/25

Expected recruitment end date
2021-09-29, 1400/07/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of a mixture of plant extracts and placebo on the severity of symptoms in patients with irritable bowel syndrom: A randomized double blind clinical trial

Public title
Effectiveness of herbal mixture in IBS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People in the age range of 18 to 65 years Written informed consent People with a definitive diagnosis of IBS based on the Rome Criteria
Exclusion criteria:
Any concomitant illness other than IBS People who are allergic to Echinophora platyloba, Trachyspermum copticum and Zataria multiflora or other herbal medicines People who have had a history of taking herbal medicines during the last 3 months Pregnant and lactating lady
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on simple randomization, two series of numbers are obtained with the help of Random.org. Accordingly, patients who meet the conditions for entering the plan will be assigned to one of the two groups of treatment or placebo, respectively.
Blinding (investigator's opinion)
Double blinded
Blinding description
Using exactly the same forms of syrup for medicine and placebo and installing the codes extracted from the random block table on them, the participants, the main researcher, the health care personnel (doctors, nurses, etc.) who are responsible for caring for the patients, Data collectors and those evaluating the outcome are completely blinded.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University of Pharmaceutical Sciences
Street address
No.99 , at the beginning of Yakhchal Ave, Gholhak, Shariati Ave
City
Tehran
Province
Tehran
Postal code
19395-6466
Approval date
2021-05-31, 1400/03/10
Ethics committee reference number
IR.IAU.PS.REC.1399.311

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
Abdominal pain
Timepoint
Before starting the intervention and one month after that
Method of measurement
Paitient severity score questionnaire

2

Description
IBS severity score
Timepoint
Before starting the intervention and one month after that
Method of measurement
Paitient severity score questionnaire

Secondary outcomes

1

Description
Blowing
Timepoint
Before starting the intervention and one month after that
Method of measurement
Paitient severity score questionnaire

Intervention groups

1

Description
Intervention group: Individuals who met the inclusion criteria will take a drug formulated with a mixture of Echinophora platyloba, Trachyspermum copticum and Zataria multiflora extracts, prepared in Yas Drug Pharmacy, at a dose of 5 ml, 3 times a day for a month.
Category
Treatment - Drugs

2

Description
Control group: Individuals who met the inclusion criteria will take a placebo formulated without a mixture of plant extracts prepared in Yas Drug Pharmacy, at a dose of 5 ml, 3 times a day for a month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bouali hospital
Full name of responsible person
Zeinab sadat Tabaee Fazli
Street address
Damavand Ave; Emam Hosein square
City
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Phone
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Bouali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zeinab sadat Tabaee Fazli
Street address
No.99 , Yakhchal Ave, Gholhak , Shariati Ave
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Phone
+98 21 2264 0051
Email
zeinabfazli96@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yas Daru Knowledge base Pharmaceutical Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ramin Abrishami
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Zeinab sadat Tabaee Fazli

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Unit 1, No.13, Shifte alley, after Hedayat square, Darus

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Person responsible for updating data

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Position
Student

Latest degree
A Level or less

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
There is no more information

When the data will become available and for how long
There is no more information

To whom data/document is available
There is no more information

Under which criteria data/document could be used
There is no more information

From where data/document is obtainable
There is no more information

What processes are involved for a request to access data/document
There is no more information

Comments