

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 Tabaei 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 syndrome: 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

Patient severity score questionnaire

### 2

#### Description

IBS severity score

#### Timepoint

Before starting the intervention and one month after that

#### Method of measurement

Patient severity score questionnaire

## Secondary outcomes

## 1

### Description

Blowing

### Timepoint

Before starting the intervention and one month after that

### Method of measurement

Patient 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 Tabaei Fazli

#### Street address

Damavand Ave; Emam Hosein square

#### City

Tehran

#### Province

Tehran

#### Postal code

17117

#### Phone

+98 21 3334 8036

#### Fax

#### Email

Bouali.hospital96@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Islamic Azad University

### Full name of responsible person

Zeinab sadat Tabaei Fazli

### Street address

No.99 , Yakhchal Ave, Gholhak , Shariati Ave

### City

Tehran

### Province

Tehran

### Postal code

19395-6466

### 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

#### Street address

No 99, Yakhchal Ave , Gholhak , Shariati Ave

#### City

Tehran

#### Province

Tehran

#### Postal code

19395-6466

#### Phone

+98 21 2264 0051

#### Email

r\_abrishami@iaups.ac.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zeinab sadat Tabaei Fazli

**Position**

student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1943894471

**Phone**

+98 21 2255 6336

**Email**

zeinabfazli96@yahoo.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zeinab sadat Tabaei Fazli

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

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**Email**

zeinabfazli96@yahoo.com

## **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**