Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Saffron vs Fluoxetine in irritable bowel syndrome patients: A double – blind controlled clinical trial

Protocol summary

Summary

The main target of the study is to determine and compare the effect of Fluoxetine 20 mg/day with safron 15 mg/day on symptoms of patients with moderate to severe irritable bowel syndrome. 50 patients with moderate to severe irritable bowel syndrome who refer to Gastero-intestinal clinic of Imam Khomeini hospital (Tehran, Iran) will be recruited if meet the eligibility criteria. The patients will be randomly assigned into one of the following groups to receive Fluoxetine 20 mg/day or safron 15 mg/day, for 6 weeks. The severity of symptoms,will be measured at the baseline and second, 4th and 6th week after the intervention. Symptoms will also be registered daily. The follow-up period will be 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509081556N81**
Registration date: **2015-09-16, 1394/06/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Saffron vs Fluoxetine in irritable bowel syndrome patients: A double – blind controlled clinical trial

Public title

Saffron in irritable bowel syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years old; IBS diagnosis through ROME III criteria; moderate to severe symptoms through severity of symptom questionnaire. Exclusion criteria: diagnosis of any organic disease related to symptoms during the study; psychological disorders taking any other psychotropic drugs during 4 weeks before entering to the trial; history of taking fluoxetine for treatment of IBS in the past; presence of any contraindications for taking fluoxetine; low compliance; severe complications due to fluoxetine; pregnancy or breastfeeding at the beginning or during the trial.

Age

From **18 years** old to **65 years** old

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshvarz Blvd
City
Tehran
Postal code
Approval date
2015-07-23, 1394/05/01
Ethics committee reference number
IR.TUMS.REC.1394.670

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
Severity of symptom
Timepoint
Baseline and weeks 2-4-6 after beginig of treatment
Method of measurement
IBS-SSS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Capsule Saffron 15mg/day as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Capsule Fluoxetine 20 mg/day for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Prof. Reza Malekzadeh
Street address
Keshavarz blvd. Imam Khomeini Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Masoud Yunesian
Street address
Keshvarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty

Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty