Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Efficacy of Sertraline on the Symptoms and Quality of Life in Irritable Bowel Syndrome Patients

Protocol summary

Study aim
Evaluation of the efficacy of sertraline on symptoms and quality of life in patients with irritable bowel syndrome

Design
Randomized clinical trial with control group, with parallel groups

Settings and conduct
Sixty patients with irritable bowel syndrome after a clinical diagnosis by a gastroenterologist will be referred to a psychiatrist, in order to assess the presence of comorbid psychiatric disorders through a clinical structured psychiatric interview. Then, the patients will be randomly allocated in the two case and control groups in the absence of exclusion criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The presence of ROME III diagnostic criteria for the diagnosis of irritable bowel syndrome; Written consent for participation in the study Exclusion criteria: Age under 18 years; The presence of warning signs such as chronic fever, weight loss, gastrointestinal bleeding; Use of any drug that affects the bowel function (such as laxatives, anti diarrhea and antibiotics) within one month before entering the study; Known cases of lactose intolerance; Comorbidity of other serious physical or psychological illnesses, serious suicidal thoughts and substance dependence that affect the treatment of patients and their compliance with the study protocol

Intervention groups
Intervention group: Daily 50-200 milligram Sertraline manufactured in Doctor Abidi Pharmaceutical Company and 200 milligram Clofac (Mebeverine Hydrochloride) each night for 8 weeks Control group: 200 milligram Clofac (Mebeverine Hydrochloride) each night for 8 weeks

Main outcome variables
Severity of irritable bowel syndrome symptoms; The patients quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150630022991N11**
Registration date: **2018-03-22, 1397/01/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-22, 1397/01/02**
Update count: **0**

Registration date
2018-03-22, 1397/01/02

Registrant information

Name
Sussan Moudi

Name of organization / entity
Babol University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 11 3236 5683

Email address
sussan.mouodi@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-05, 1396/10/15

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Sertraline on the Symptoms and Quality of Life in Irritable Bowel Syndrome Patients

Public title
Efficacy of Sertraline in Irritable Bowel Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The presence of ROME III diagnostic criteria for the diagnosis of irritable bowel syndrome Written consent for participation in the study
Exclusion criteria:
Age under 18 years Allergy to sertraline The presence of warning signs such as chronic fever, weight loss, gastrointestinal bleeding Pregnancy and breast feeding Use of any drug that affects the bowel function (such as laxatives, anti diarrhea and antibiotics) within one month before entering the study Known cases of lactose intolerance Comorbidity of other serious physical or psychological illnesses, serious suicidal thoughts and substance dependence that affect the treatment of patients and their compliance with the study protocol
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random allocation
Blinding (investigator's opinion)
Not 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 Babol University of Medical Sciences
Street address
Ganjafrooz Avenue, Babol
City
Babol
Province
Mazandaran
Postal code
4136747176
Approval date
2017-08-27, 1396/06/05
Ethics committee reference number
MUBABOL.HRI.REC.1396.52

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 irritable bowel syndrome symptoms
Timepoint
At baseline, and the fourth and eighth weeks after the intervention
Method of measurement
Visual Analogue Scale (VAS)

2

Description
The patients quality of life
Timepoint
At baseline, and the eighth week after the intervention
Method of measurement
SF-36 quality of life questionnaire

Secondary outcomes

1

Description
Adverse drug side effects
Timepoint
The fourth and eighth weeks after the intervention
Method of measurement
Medical visit

Intervention groups

1

Description
Intervention group: Daily 50-200 milligram Sertraline manufactured in Doctor Abidi Pharmaceutical Company and 200 milligram Clofac for eight weeks

Category
Treatment - Drugs

2

Description
Control group: Daily 200 milligram Clofac for eight weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Sussan Moudi, MD
Street address
Ayatollah Rouhani Hospital, Ganjafrooz avenue, Babol
City
Babol
Province
Mazandaran
Postal code
4718747415
Phone
+98 11 3219 0624
Email
sussan.mouodi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi, MD, PhD
Street address
Babol University of Medical Sciences, Ganjafrooz avenue, Babol
City
Babol
Province
Mazandaran
Postal code
4718747415
Phone
+98 11 3236 8823
Email
rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
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
Babol University of Medical Sciences
Full name of responsible person
Sussan Moudi, MD
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Department of Psychiatry, Shahid Yahyanejad Hospital, Babol
City
Babol
Province
Mazandaran
Postal code
4718747415
Phone
+98 11323268823
Fax
Email
sussan.mouodi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Sussan Moudi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Department of Psychiatry, Shahid Yahyanejad Hospital, Babol
City
Babol
Province
Mazandaran
Postal code

4718747415

Phone

+98 11323268823

Fax

Email

sussan.mouodi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi, MD

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Department of Psychiatry, Shahid Yahyanejad Hospital, Babol

City

Babol

Province

Mazandaran

Postal code

4718747415

Phone

+98 11 3219 0624

Fax

+98 11 3219 0624

Email

sussan.mouodi@gmail.com

Web page address

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information related to the main outcome variables can be shared.

When the data will become available and for how long

After publication of the final manuscript

To whom data/document is available

Researchers in universities

Under which criteria data/document could be used

Subsequent to the request of the researchers, the relevant documentation will be sent.

From where data/document is obtainable

Sussan Mouodi with email address sussan.mouodi@gmail.com

What processes are involved for a request to access data/document

Within a maximum of one month after receiving a request email

Comments