

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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, Ganjafrroz 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, Ganjafrroz 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

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Psychiatrics

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+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

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Psychiatrics

Street address

Department of Psychiatry, Shahid Yahyanejad
Hospital, Babol

City

Babol

Province

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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