Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of sertraline and nortriptyline on improvement of abdominal pain and distention in patients with irritable bowel syndrome: A randomized clinical trail

Protocol summary

Summary

Objectives: the objective of this trial is to compare the effects of Sertraline and Nortriptyline on irritable bowel syndrome patients for relief of abdominal pain. Design: a triple blind, randomized clinical trail. Setting and conduct: in this stuy, 30 patients with irritable bowels syndrome are randomly assigned to receive Sertraline or Nortriptyline. Before allocation, all patients were completed Beck questionnaire for screening of depression. Major Inclusion and Exclusion criteria: the main exclusion criteria were the use of analgesic drugs; pregnant women; breast feeding; patients with major depressive disorder (MDD) according to DSM-IV-TR; gastrointestinal bleeding; presence of any finding in favor of organic disorders in the lab tests; or organic disorder in colonoscopy of high risk patients. Intervention: Sertraline (tablet 25mg oral for 7 days and then 50 mg oral) as intervention and Nortriptyline (tablet 10 mg oral) for control group once daily for 8 weeks. Main outcome measures variables: abdominal pain, the IBS,Symptom Severity Scoring measure (IBS,SSS), which contains five 100 point scales, that assess the severity of abdominal pain, the frequency of abdominal pain, the severity of abdominal distention, dissatisfaction with bowel habits, and interference with quality of life, incomplete evacuation, and bloating are measured and compared between groups at the baseline and 8 weeks after the intervention.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201504131647N3**
Registration date: **2015-06-11, 1394/03/21**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-06-11, 1394/03/21

Registrant information

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Name of organization / entity
Shahroud University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-08-01, 1391/05/11

Expected recruitment end date

2013-07-01, 1392/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sertraline and nortriptyline on improvement of abdominal pain and distention in patients with irritable bowel syndrome: A randomized clinical trail

Public title

Effect of sertraline and nortriptyline on irritable bowel

syndrome: A randomized clinical trail

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of clinical findings of irritable bowel syndrome according to ROME II criteria; including abdominal pain or refferal pain at least 3 days in every months. Exclusion criteria: use of analgesic drugs; pregnant women; breast feeding; patients with major depressive disorder (MDD) according to DSM-IV-TR; gastrointestinal bleeding; presence of any finding in favor of organic disorders in the lab tests; or organic disorder in colonoscopy of high risk patients.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study patients were allocated to A and B according to permuted block randomization method,with block size of 4. For preventing the selection bias we used a concealment method.the A and B sequences were put to a closed envelopes. After assignment the patients were introduced to drug store for receiving their treatments.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Hafte Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.

City

Shahroud

Postal code

3614773955

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

910-5

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 abdominal pain

Timepoint

prior to intervention and 8 weeks after intervention

Method of measurement

Questionnaire (IBS, Symptom Severity Scoring) and visual scale of pain

2

Description

severity of abdominal distension

Timepoint

prior to intervention and 8 weeks after intervention

Method of measurement

Questionnaire (IBS, Symptom Severity Scoring) and visual scale of pain

3

Description

frequency of abdominal pain

Timepoint

prior to intervention and 8 weeks after intervention

Method of measurement

Questionnaire (IBS, Symptom Severity Scoring) and visual scale of pain

4

Description

dissatisfaction with bowel habits

Timepoint

prior to intervention and 8 weeks after intervention

Method of measurement

Questionnaire (IBS, Symptom Severity Scoring) and visual scale of pain

5

Description

interference with quality of life

Timepoint

prior to intervention and 8 weeks after intervention

Method of measurement

Questionnaire (IBS, Symptom Severity Scoring)

Secondary outcomes

1

Description

Bloating

Timepoint

prior to intervention and 8 weeks after intervention

Method of measurement

IBS, Adequate Relief (IBS, AR)

Intervention groups

1

Description

Intervention group: Sertraline, tablet 25mg oral for 7 days and then 50 mg oral, once daily for 8 weeks. Sertraline, Sobhandarou, tablet 50 mg, Iran.

Category

Treatment - Drugs

2

Description

Control group: Nortriptyline (Sobhan Darou, Iran), tablet 10 mg oral, once daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital and Khatamol anbiya Hospital

Full name of responsible person

Dr Hamid Vahedi

Street address

Hafte Tir Square, Shahroud University of Medical Sciences, Shahroud, Iran.

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research; Shahroud University of Medical Sciences

Full name of responsible person

Dr Hamid Vahedi

Street address

7 Tir Sq, Shahroud University of Medical Sciences

City

Shahroud

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research; Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr Hamid Vahedi

Position

MD, gastroenterologist

Other areas of specialty/work

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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