Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

comparative survey of the effect of doxepin and nortriptyline on diarrhea-predominant irritable bowel syndrome

Protocol summary

Summary

The objective of this randomized triple blind controlled trial is to compare the effects of Doxepine and Nortriptyline on diarrhea predominant irritable bowel syndrome. In this stuy, 50 patients with IBS are randomly assigned to receive Doxepin or Nortriptyline, a tablet per day, orally, for two months. Abdominal pain, mucus in the stool, incomplete evacuation, and bloating are measured and compared between groups at the baseline and one and two month after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903114017N3**
Registration date: **2010-06-12, 1389/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-06-12, 1389/03/22

Registrant information

Name

Hosseinali Habibinejad

Name of organization / entity

Islamic Azad University of Qom

Country

Iran (Islamic Republic of)

Phone

+98 21 7745 4051

Email address

ghadir@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Young Researchers Club

Expected recruitment start date

2010-06-04, 1389/03/14

Expected recruitment end date

2010-09-20, 1389/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative survey of the effect of doxepin and nortriptyline on diarrhea-predominant irritable bowel syndrome

Public title

Effect of doxepin and nortriptyline on irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of diarrhea predominant irritable bowel syndrome according to ROME criteria
Exclusion criteria: Gastrointestinal bleeding, More than 5% weight loss in the last 6 months, presence of any finding in favor of organic disorders in the lab tests or organic disorder in colonoscopy of high risk patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qom University of Medical Sciences
Street address
Saheli Ave., Qom
City
QOM
Postal code
Approval date
empty
Ethics committee reference number
263/ა

Health conditions studied

1

Description of health condition studied
diarrhea predominant irritable bowel syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
abdominal pain
Timepoint
prior to intervention- 1 month after intervention- 2 month after intervention
Method of measurement
visual scale of pain

2

Description
mucus in the stool
Timepoint
prior to intervention- 1 month after intervention- 2 month after intervention
Method of measurement
visual scale of mucus in the stool

3

Description
Bloating
Timepoint
prior to intervention- 1 month after intervention- 2 month after intervention
Method of measurement
visual scale of bloating

4

Description
Incomplete evacuation
Timepoint
prior to intervention- 1 month after intervention- 2 month after intervention
Method of measurement
visual scale of Incomplete evacuation

Secondary outcomes

1

Description
somnolence
Timepoint
prior to intervention-1 month after intervention-2 months after intervention
Method of measurement
visual scale of somnolence

2

Description
constipation
Timepoint
prior to intervention-1 month after intervention-2 months after intervention
Method of measurement
visual scale of constipation

3

Description
urinary retention
Timepoint
prior to intervention-1 month after intervention-2 months after intervention
Method of measurement
visual scale of urinary retention

4

Description
tachycardia
Timepoint
prior to intervention-1 month after intervention-2 months after intervention
Method of measurement
pulse examination

Intervention groups

1

Description
Doxepin,tablet 10 mg oral,once daily for 2 months
Category
Treatment - Drugs

2

Description
Nortriptyline,tablet 10 mg oral,once daily for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Ghadir's office
Full name of responsible person
Dr Mohammad Reza Ghadir
Street address
Dr Ghadir's office, 2nd floor, Sepah Sq., Jomhouri blvd., Amin Blvd.
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Young Researchers Club
Full name of responsible person
Shokouhi
Street address
Malek Ave., Shariati Ave., Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Young Researchers Club
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
Islamic Azad University of Qom
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Hosseinali habibinejad
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Person responsible for updating data

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Email

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Web page address

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