

# 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

Young Researchers Club

#### 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 study, 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.

#### 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

#### General information

#### Scientific title

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

#### 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

#### 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

#### 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

#### 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)

#### Recruitment status

Recruitment complete

#### Funding source

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

263/3

## 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., Jomhuri 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

##### Full name of responsible person

Hosseinali habibinejad

##### Position

General Practitioner

##### Other areas of specialty/work

##### Street address

No.143, 62 Alley, Azar Ave.

##### City

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##### Postal code

##### Phone

+98 25 1720 8392

##### Fax

##### Email

ali.medicine@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Qom University of Medical Sciences

##### Full name of responsible person

Dr Mohammadreza Ghadir

##### Position

Gastroenterologist

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

#### Contact

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Islamic Azad University of Qom

##### Full name of responsible person

Hosseinali Habibinejad

##### Position

General practitioner

##### Other areas of specialty/work

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**Fax**

**Email**

ali.medicine@yahoo.com

**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*