# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Comparison of the effect of duloxetine and imipramine on diarrhea improvement in outpatients with irritable bowel syndrome with diarrhea predominance

## Protocol summary

**Study aim**
Use of duloxetine compared with imipramine in the treatment of diarrhea in patients with irritable bowel syndromedue to more complications of TCA

**Design**
Clinical trial with controled group with parallel and randomizied group

**Settings and conduct**
48 Patients with irritable bowel syndrome,including 24 females and 24 males,were examined by gastroenterologist and based on Rome III Criteria for definitive diagnosis of irritable bowel syndrome after rejecting other diagnosis and have diarrhea after obtaining the consent they enter the study.Randomization will take place in 4 groups based on permutation block randomization and base on 2 blocks.patients in control group treated with dicyclomine and imipramine at the dose of 10 mg will increase to 25 mg 2 weeks if not treated. and in the case group treated with dicyclomine and duloxetine at the dose of 20 mg will increase to 60 mgif needed.patients results are compared before and 3 months after treatment{mostly diarrhea}

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:patients with irritable bowel syndrome and diarrhea perdominance base on Rome III criteria Exclusion criteria:pregnancy/lactation/history ofany bowel surgeryexcept appandectomy/Dissatisfaction to be include in the study/Drugs use interferes with duloxetine/diabet/Infectious diarrhea/Inflammatory bowel disease

**Intervention groups**
Patients were randomly divided into two groups of 24,which were given to a drug group with duloxetine 20 mg and if as need increase to 60mg in 2 weeks and another group with Imipramin 10 mg and if as need increase to 25 mg in 2 weeks for 3 months.

**Main outcome variables**
The number of emergency defication per day/The number of days with bloating per week/The nember of days with pain per week/Frequency of diarrhea per day

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20190703044084N1**
Registration date: **2020-02-03, 1398/11/14**
Registration timing: **retrospective**

Last update: **2020-02-03, 1398/11/14**
Update count: **0**

**Registration date**
2020-02-03, 1398/11/14

**Registrant information**
**Name**
sattar jafari
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 24 3377 0801
**Email address**
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2019-08-27, 1398/06/05
**Expected recruitment end date**
2019-11-26, 1398/09/05
**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of duloxetine and imipramine on diarrhea improvement in outpatients with irritable bowel syndrome with diarrhea predominance

**Public title**

Comparison of the effect of duloxetine and imipramine on diarrhea treatment in patients with irritable bowel syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with irritable bowel syndrome and diarrhea predominance between the ages of 18-40 years based on Rome III criteria

**Exclusion criteria:**

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study 48 patients with irritable bowel syndrome,including 24 women and 24 men,will be included in the study.Randomization will be done in 4 groups on the weber permutation block randomization basis of 4 blocks.

**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**

کمیته اخلاق دانشگاه علوم پزشکی زنجان

**Street address**

No1.Jomhori Blvd,Azadi squqre,zanjan city

**City**

zanjan

**Province**

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**Postal code**

4515613191

**Approval date**

2019-07-02, 1398/04/11

**Ethics committee reference number**

IR.ZUMS.REC.1398.074

## Health conditions studied

**1**

**Description of health condition studied**

Irritable Bowel syndrom with diarrhea perdominnace

**ICD-10 code**

Irritable

**ICD-10 code description**

K58

## Primary outcomes

**1**

**Description**

Diarrhea,abdominal pain,age,sex

**Timepoint**

Beginning of the study and 3 months later

**Method of measurement**

IBS severity score questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Dluxetine 20mg and if needed increase to 60 mg for up to 3 months and Control group:Imipramine 10mg and if needed increase to 25 mg for up to 3 months

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Zanjan Vali-e-Asr Hospital

**Full name of responsible person**

Sattar jafari

**Street address**

Vali-e-Asr squqre,Zanjan

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Vice chancellor for research,Zanjan Univercity of medical sciences
**Street address**
No1,Jomhori Blvd,Azadi square,Zanjan city
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Zanjan 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**
Zanjan University of Medical Sciences
**Full name of responsible person**
Sattar jafari
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
No more information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available