Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of ondansetron in the treatment of patients with diarrhea dominant irritable bowel syndrome (IBS)

Protocol summary

Study aim
The effect of ondansetron in treatment of patients with diarrhea dominant irritable bowel syndrome (IBS)

Design
A randomized controlled clinical trial with double blinded and randomized parallel groups

Settings and conduct
This study will be conducted in Valiasr hospital. Patients were randomly divided to two groups of intervention and control. For 2 months, the intervention group will receive imipramine and ondansetron; while control group will receive imipramine and placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with irritable bowel syndrome and diarrhea predominance based on Rome III criteria, age between 18-50 years. Exclusion criteria: Pregnancy, Lactation, Dissatisfaction to be include in the study, Any sign and symptom of inflammatory bowel disease, Psychiatric drug use, History of drugs Interaction with ondansetron, Bowel surgery except appendectomy and cholecystectomy

Intervention groups
Intervention group: 50 patients treated by Imipramine (made by Abidi Pharma Compony) daily 25 mg and ondansetron (made by Abidi Pharma Compony) 4mg 3 times per day for up to 2 months. Control group: 50 patients treated by Imipramine (made by Abidi Pharma Compony) daily 25 mg and placebo (containing Avicel and made by the School of Pharmacy) 4mg 3 times per day for up to 2 months.

Main outcome variables
Defecation urgency؛ Bloating; Pain; Diarrhea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190703044084N2**
Registration date: **2020-04-20, 1399/02/01**
Registration timing: **retrospective**

Last update: **2020-04-20, 1399/02/01**
Update count: **0**

Registration date
2020-04-20, 1399/02/01

Registrant information

Name
sattar jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3377 0801

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jafari1354@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-27, 1398/04/06

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ondansetron in the treatment of patients with diarrhea dominant irritable bowel syndrome (IBS)

Public title
Effect of ondansetron in treatment of irritable bowel syndrome (IBS)

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with irritable bowel syndrome with diarrhea predominance based on Rome III criteria Age:Between 18-50 years
Exclusion criteria:
Pregnancy Lactation Dissatisfaction to be included in the study Any sign and symptom of inflammatory bowel disease Psychiatric drug use Drugs Interaction with ondansetron including: p450 enzyme system inducers (carbamazepine, phenobarbital, phenytoin, dexamethasone, rifampicin) p450 enzyme system inhibitors (clarithromycin erythromycin ketoconazole) 3 History of any bowel surgery except appendectomy and cholecystectomy
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 100 patients with irritable bowel syndrome will be randomly studied in two groups, each including 50. Randomization in the mentioned groups will be conducted according to permuted block randomization based on quaternary blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind and placebo-controlled study. Placebo will be provided similar to androsterone in terms of taste, flavor and color, by the School of Pharmacy. The content of Placebo is Avicel. Medicines will be delivered to patients by a third person (a health care provider) who is not directly involved in the research.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Science
Street address
No 1. Jomhori boulvard, Azadi square, Zanjan city.
City
Zanjan
Province
Zanjan
Postal code
۴۵۱۵۶۱۳۱۹۱
Approval date
2019-06-26, 1398/04/05
Ethics committee reference number
IR.ZUMS.REC.1398.121

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome with diarrhea
ICD-10 code
K58.0
ICD-10 code description
Irritable bowel syndrome with diarrhea

Primary outcomes

1

Description
Defecation urgency
Timepoint
Beginning of the study and 2 months later
Method of measurement
checklist; irritable bowel syndrome severity score questionnaire

2

Description
pain
Timepoint
Beginning of the study and 2 months later
Method of measurement
checklist; irritable bowel syndrome severity score questionnaire

3

Description
bloating
Timepoint
Beginning of the study and 2 months later
Method of measurement
checklist; irritable bowel syndrome severity score questionnaire

4

Description
diarrhea
Timepoint
Beginning of the study and 2 months later
Method of measurement
Bristol stool scale form; checklist; irritable bowel syndrome severity score questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 50 patients treated by Imipramine (made by Abidi Pharma Compony) daily 25 mg and ondansetron (made by Abidi Pharma Compony) 4mg 3 times per day for up to 2 months.
Category
Treatment - Drugs

2

Description
Control group: 50 patients treated by Imipramine (made by Abidi Pharma Compony) daily 25 mg and placebo (containing Avicel and made by the School of Pharmacy) 4mg 3 times per day for up to 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr hospital
Full name of responsible person
Sattar Jafari
Street address
Hazrat Valiasr Training Center, Valiasr Square, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
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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
Internal Medicine
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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